Exhibit D

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

Case No.: 2:13-cv-04457 MDL NO. 2326

VIDEO DEPOSITION OF BRIAN J. FLYNN, MD August 29, 2014

BOSTON SCIENTIFIC CORPORATION, PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION
Related to
AMBER COMER.

A P P E A R A N C E S:

For Plaintiff:

SEAN O. MCCRARY, ESQUIRE
sean.mccrary@ahw-law.com
Andrus Wagstaff, PC
7171 West Alaska Drive
Lakewood, Colorado 80226
(303) 376-6360

For Defendant:

ANDREW H. MYERS, ESQUIRE
myers@wtotrial.com
Wheeler Trigg O'Donnell, LLP
370 Seventeenth Street, Suite 4500
Denver, Colorado 80202
(303) 244-1800

APPEARANCES: (Cont.)

For Witness:
GREGORY R. PICHE, ESQUIRE
Singularity Legal, PLLC
3144 Newton Street
Denver, Colorado 80211
(303) 668-4240

Also Present: Adam Johnston, Videographer

Pursuant to Notice and the Colorado Rules of Civil Procedure, the video deposition of BRIAN J. FLYNN, MD called by Plaintiff, was taken on Friday, August 29, 2014, commencing at 7:10 AM at 12631 17th Street, Fifth Floor, Aurora, Colorado, before Martha Loomis, Certified Shorthand Reporter and Colorado Notary Public.

I N D E X

VIDEO DEPOSITION OF BRIAN J. FLYNN, MD

THE VIDEOGRAPHER: We are now on the record. My name is Adam Johnston. I am a videographer for Golkow Technologies. Today's date is August 29, 2014. The time is 7:10 a.m. This video deposition is being held at 12631 East 17th Avenue, Room 5500, Aurora, Colorado. It's in the matter of Amber Comer versus Boston Scientific Corporation for the U.S. District Court, the Southern District of West Virginia. The deponent is Brian J. Flynn, M.D.

Counsel, please identify yourselves for the record.

MR. MCCRARY: My name is Sean McCrary with the Andrus Wagstaff firm in Denver representing Plaintiff Corner.

MR. MYERS: Andrew Myers with Wheeler Trigg O'Donnell on behalf of Boston Scientific.

MR. PICHE: Greg Piche here on behalf of the deponent.

THE VIDEOGRAPHER: The court reporter is Martha Loomis. She will now swear in the witness.

P R O C E E D I N G S

BRIAN J. FLYNN, MD,

having been duly sworn to state the whole truth, testified as follows:

EXAMINATION

BY MR. McCRARY:

Q. Good morning, Dr. Flynn. My name is Sean McCrary. I'm an attorney for one of your patients, Amber Comer.

Did you receive a copy of a notice of deposition to appear today?

A. I did.

Q. I got a copy for you right here. We're going to mark that as Exhibit 1.

(Exhibit 1 marked for identification.)

MR. McCRARY: Andrew, do you need one?

MR. MYERS: No, that's fine.

(BY MR. McCRARY) Q. Do you see on the second page of that document, Doctor, it asked you to bring a couple of things with you today?

A. I do.

Q. Can we just go through those, and I'll ask you whether or not you brought each one of those requests on that document.

A. Okay. So bullet point A, medical records and in-hospital records, I have that directly available.

The University no longer has a paper chart. We have electronic charts. So I have my laptop here and access to Epic, which is our electronic medical record, EMR. So I have all those records readily available, and certainly I can print anything if you would like at any point.

Page 6

I do not have any photographs or slides or questionnaires. I don't have any information sheets. I don't keep any personal records on my patients; everything is a shared chart with the University so I don't have a personal office chart. Everything's the University of Colorado Hospital chart.

In terms of billing statements and insurance issues, I don't have any copies of that. I have not had any correspondence with the Plaintiff electronically or written communication.

And with respect to bullet point B, I don't have any emails to Boston Scientific as it pertains to this case or this product, Lynx. I do have a copy of my CV if you'd like me to submit that as an exhibit.

Q. Sure.

A. This is an updated copy. And I printed that out this morning, so that is the most recent copy of my CV. Let's see.

Lastly, bullet point 3, I've never used this product Lynx, so I don't have any, any information for users or instructions to user, patient brochures, or marketing literature from Boston Scientific.

Q. All right. Thanks, Doctor. And I probably should have asked you this at the outset, but have you ever been deposed before?

Page 7

A. I have.

Q. And so you're familiar with the process, and that you need to wait for me to finish before you answer? And if defense -- Defense Attorney has an objection you need to let him get that out there and the same with your attorney, before you give your answer?

A. Yes. I'm familiar with the process.

Q. Okay. In that case, why don't we start by just taking a look at your CV here. Is this the only copy you brought with you?

A. I have an electronic copy right in front of me as well.

Q. I'll go ahead and mark it and that way we'll both get a copy, and I'll let you look at that as you go.

(Exhibit 2 marked for identification.)

Q. And I just wanted you to give us a brief summary of your background, and how you ended up as a physician here today.

A. Well, I'm Dr. Brian Flynn. And I am the co-director of female pelvic medicine reconstructive surgery at the University of Colorado. I'm associate professor here of surgery and urology.

And I've been a faculty member here for more than 12 years. I came here in 2002 after finishing my fellowship at Duke University in female pelvic medicine and

Page 8

reconstructive surgery.

I started out as an assistant professor and was promoted to associate professor at my eighth year. And I'm being considered for full professor.

My practice is largely in female pelvic medicine, but I do male reconstructive surgery as well.

Q. Okay. And correct me if I'm wrong. My understanding is that you receive a lot of referrals when other physicians around the region have mesh complications. Is that accurate?

A. I receive a lot of referrals for a variety of complaints, mesh complications included.

Q. Would you say that you see more mesh complications than most gynecologists or urogynecologists in this area?

MR. MYERS: Objection to form.

A. I see a lot of complications. I'm not familiar with what other people's numbers are. But I know I'm very busy in that part of my practice. It's a significant part of my practice. I've done -- I have an interest in that area.

(BY MR. McCRARY) Q. Have you ever done any research involving pelvic mesh?

A. Can you be more specific about research?

Q. Have you ever performed any studies involving pelvic mesh?

A. Clinical studies in terms of prospective randomized

Page 9

studies or industry sponsored studies, no. In terms of retrospective case series, yes, looking at my own experiences with mesh.

I've looked at my experience using TVT Secur is one product that I've written about. And I've published videos on TVT Abbrevo. I have published a video on Prolift is another product that I've published a video on.

And with respect to mesh complications, I've written about that. I've written two major articles. One was an update for the American Urologic Association. And another article was a recent article in 2013 I believe in the International Urogynecology looking at complications from midurethral slings.

Most of my research is retrospective case series. It's not bench work. I've never done any laboratory work or bench science, or any kind of biomaterial scientific research on any of these products.

Q. So does that then mean that you're essentially going back and looking at the cases that you've seen, and quantifying how often you see certain occurrences with pelvic mesh? Is that accurate?

A. Yes, that's accurate.

Q. Okay. And you mentioned that you did a video. What were you, what was the purpose of the video? Was it a training video?

Page 10

A. A few purposes. One is as a faculty member here we're encouraged to present our data and do research and interact at scientific meetings, and so the videos were part of a scientific program that was presented at the American Urologic Association.

One of the videos, one was presented at the south central section of the American Urologic Association. Those videos were done with our residents and fellows.

So the videos were done to present our technique, and to help guide physicians on how to do the procedure properly. That is the majority of the videos.

There is one video that was done specifically for Ethicon. That was the TVT Abbrevo video. That is on their website. That's my video; it's still on the website today.

And that video was done for online training as part of their physician portal. It's not viewable by consumers, but just for, for physicians who have a portal. They can go online and look at the video.

And it was shared at their different teaching courses they have.

Q. So I take it, then, that you have been retained to work for -- is it, did you say Johnson and Johnson? Or was it --

A. I had been during that time, yes.

Q. And it was Johnson and Johnson?

Page 11

A. Well, Ethicon is their surgical division. Johnson and Johnson is the parent company.

Q. Okay. And what was the scope of your contract with that company?

A. I don't have any existing contracts with them. I have not had a contract with them in at least a few years. I'd have to look back at the exact records, Sean.

But at the time you got paid for any consulting work that you did for them. So we agreed on a rate for me to do that video for them.

Q. Okay. And so basically is it accurate that they asked you to help with physician training?

A. That's accurate, yes.

Q. Okay.

A. I was, you know, what you would consider a preceptor.

Q. Okay. And so have, has, has Ethicon ever sent other surgeons to come watch you perform surgery?

A. Yes.

Q. And did they come here to Denver? Or did you go somewhere, and the other physicians also came there and watched you there?

A. Both.

Q. Okay. Do you recall where you went?

A. For what specific event?

Page 12

Q. For training.

A. Mostly in the western United States. They would have a training facility that they would rent out. They don't own the facility, but there's different training facilities, one here in Aurora at Science Care and another facility in Phoenix and another one in California.

So those were the three primary places that we would have what we'd call a lab where we'd train physicians on new products and old products using a cadaver, using videos, using tutorials, PowerPoint presentations.

Q. Were you involved at all in the drafting of any of those materials, the PowerPoints, things like that?

A. Very limited role. For the most part their professional educational department would develop most of the literature.

Q. Has Ethicon or any other vaginal mesh device manufacturer ever reached out to you with questions?

MR. MYERS: Objection to form.

A. Yeah, You'd have to be more specific.

(BY MR. McCRARY) Q. Have they ever reached out to you with questions about ways to improve implantation technique?

A. That's a very open-ended question, Sean. When you say "reach out," can you --

Q. Basically I want to know if, you know, these

Page 13

companies, they have what we refer to as key opinion leaders, who -- which are physicians that they respect in a field.

If they're either developing a new product or if they have, you know, maybe some new literature that comes out that may raise some eyebrows and they have questions about that literature they'll, they'll ask some of their key opinion leaders their thoughts.

Basically, what I'm wondering is if you're one of those people that Ethicon reached out to for advice when they were developing their mesh products?

A. I was, yes.

Q. Okay. And do you recall any -- anything specifically that Ethicon asked you about?

A. I don't remember specific questions. This would have been in around 2008. And I didn't have one-on-one conversations, you know.

When we would have these courses a number of the preceptors would get together with representatives from Ethicon. And there may be an open discussion. But, you know, people would bring ideas and talk about how the products were performing and how the -- what kind of outcomes everyone was getting.

Q. And have you trained any of the surgeons here at UC Denver?

A. I have.

Page 14

Q. Who specifically?
A. I've worked with Dr. Karlotta Davis. I've worked with Dr. Jaime Arruda. All my residents and fellows, they're all in training. I've trained over 25 residents and seven fellows.
I've worked with people in all the departments, really. That's one of our roles here. We collaborate pretty actively with a number of the divisions and departments.
Q. And do you use pelvic mesh today?
A. I do.
Q. What products do you use?
A. I use a variety of products. I use mesh for sacrocolpopexy. I use the American Medical Systems' IntePro mesh and also Boston Scientific's Upsylon mesh. And then with respect to transvaginal cases, I don't use any transvaginal mesh prolapse kits, but I do midurethral slings.
Q. And what sling do you use?
A. I use the TVT Exact product and the Boston Scientific Advantage Fit product.
Q. And does your decision as to which of those products you use, is that a patient specific thing?
A. That, and a Hospital decision making. The hospital has a products committee. And so a lot of this is determined on what the hospital has available to the physicians.
Q. How long have you been doing female reconstructive

Page 15

surgery, pelvic reconstructive surgery?
A. Not including my residency and fellowship, more than 12 years.
Q. Okay. And have you used vaginal mesh during that entire 12 years?
A. Yes.
Q. Okay. When you were in residency, did they teach you how to use vaginal mesh?
A. Yes.
Q. Was vaginal mesh a new thing at that time?
A. It was relatively new. 1998 was when Ulf Ulmsten introduced the TVT to the United States, and I probably started performing that in around '99 or 2000.
Q. And is that the, that's the product that you learned to use, or the procedure?
A. The TVT was the first product really involving pelvic floor mesh. And yes, I used that product as a resident and as a fellow, and was -- used it early in my practice here.
Q. Have you ever used the ProteGen device?
A. I've seen some of those cases as a resident, but I didn't actively participate in that, and I've never used that independently in my own practice.
But from around '95 to '98 we had a doctor, Wen Yap, who was one of my mentors, who I may have assisted him

Page 16

on some ProteGen cases. But I was not the attending physician for that.
Q. Do you know anything about how medical devices used to treat incontinence are cleared by the FDA?
A. I'm familiar that there's different processes, some more rigorous than others.
Q. And is that your -- is that the gist of your understanding of that process?
MR. MYERS: Objection to form.
(BY MR. McCRARY) Q. It's that it's basic --
A. You have to be more specific on that.
Q. Do you understand that there's a difference between a product being approved by the FDA and being cleared by the FDA?
A. Yes. There's the 510(k) process and the 522 process. And the different products, depending on which schedule they are, might have more investigation than others.
Q. And with regards to pelvic mesh in general, is it your understanding that those products have all been cleared through the 510(k) process?
A. I can't speak of all of the products. I'm familiar with the products that I use and how they're approved.
I think it's important for physicians to understand the research behind the products that they're using. But

Page 17

there's too many products out there for me to comment on how all of them are approved.
Q. Do you think any pelvic mesh products have ever been approved through the premarket approval process?
A. You mean the 510(k) process? Is that considered premarket?
Q. No. That's actually, that's two different things, which is why I'm asking that question.
A. I don't know the exact specifics then. I know that, you know, I know that there's different processes and what they're called. And what -- the FDA looks at them. I'm not exactly familiar with the process.
Q. So you don't consider yourself an FDA expert?
A. No, certainly not.
Q. Have you ever worked with the FDA?
A. Yes.
Q. And have you ever worked with the FDA in the capacity of pelvic mesh?
A. No.
Q. Okay.
A. I mean, I've written an update and a response to the FDA. I've interviewed the FDA when I wrote the American Urologic Association update. I had conversations with them.
But I was not working for them. I was interviewing them in trying to better understand the public

Page 18

health notification of 2008.
Q. So you, with the AUA, wrote a response to the public health notification that the FDA released? Is that what you're saying?
A. The AUA solicited me to write a response to help urologists understand the public health notification.
Q. And my understanding is that there's been two public health notifications. Is that your understanding as well?
A. There was a public health notification and then there was what they considered an update in 2011.
Q. Okay. And the first, the notification was in '07, right?
A. I believe it was '08, but maybe, maybe it was '07.
Q. Okay. And so the original FDA notification is the one that you worked with AUA in drafting a response to, not the 2011 version?
A. That's correct, yes.
Q. Okay. And what was the gist of the response that you helped draft?
A. In 2008?
Q. Um-hum.
A. Well, that's a 10-page document, Sean. I mean, we can spend a long time going over all that.
Q. And I don't want to do that. But in a nutshell,

Page 19

are you able to tell me?
A. I think the gist was that we wanted to help urologists understand how to use mesh properly in their practice, and how to recognize and treat complications effectively, how to counsel patients effectively in terms of doing their preoperative consents.
And then if complications do arise, how to communicate that effectively to the FDA.
Q. So you didn't necessarily express opinions one way or another as to your views on the use of vaginal mesh? Is that accurate?
A. That's not accurate.
Q. Okay. Well, can you clarify that for me?
A. You know, I wrote a 5,000 word document, so I got to believe that a lot of my opinions are in that document.
So, I mean, the AUA is very careful about asking experts to separate what is considered their opinion versus what is considered the standard of care or what's considered medical science.
So the AUA update is a product that the AUA puts out. But it's not a scientific article; it's not anything more than an update. So it's a review of the literature and a summary. There's 50 references in that. There's some study questions at the end.
The update is really a tool. It's a teaching tool

Page 20

for residents and practicing physicians. It's a CME document, so that urologists can get credit after reviewing that and answering the questions.
So I got to say that there is a lot of my own personal feelings in that document.
Q. Okay. And I think I heard you mention, when you were discussing the document that you helped draft, that part of it was helping physicians become more aware of how to talk to their patients about the potential risks of the procedure. Is that an accurate description?
A. Yes.
Q. Okay. What I want to know is whether or not your -- I guess you could call it your risk-benefit analysis has changed from when you first started using meshes to today based on the experiences that you've had.
MR. MYERS: Objection to form.
A. Yes. Can you repeat the question?
(BY MR. McCRARY) Q. Yes. So you mentioned that part of the document that you drafted was to help clinicians better discuss with their patients the risks of these procedures. Is that right?
A. Yes.
Q. Okay. So what I want to know is, has your experience over the last 12 years using these products, did that help you in drafting that update for other

Page 21

clinicians to help them discuss with their patients the risks?
A. I think any physician that's been in practice for a number of years gets more experienced at counseling patients and understanding disease and pathophysiology and incontinence specifically.
So I think just from my own clinical experience I became better from 2008 to 2014 in how to perform surgery and how to counsel patients and how to select patients properly for specific procedures.
Q. Are you more aware today of any specific complications associated with the use of mesh for treatment of incontinence than you were say ten years ago?
A. Yes.
Q. What sort of complications would that include?
A. There's a number of complications that can occur with incontinence surgery. And then there's complications that are unique to transvaginal mesh.
And I think the ones that are not unique to mesh that are known to occur with any incontinence procedure I'm probably as familiar now as I was then. But maybe some of the more unique complications we're more aware of, and we've been more, we've been made aware of better through periodic review and research.
I believe that -- I can't think of one specific

Page 22

complication; maybe we're just more aware of the incidence and the prevalence of the diseases and the complications.
Q. Do you think you're more aware, I mean, are you more aware that the incidence rates are maybe greater than you originally thought they were?
MR. MYERS: Is this over a ten-year time period? I just, I can't remember what the question is.
MR. McCRARY: I want to know from when he first started using mesh to today.
MR. MYERS: Okay.
MR. McCRARY: When he wrote his letter that's helping other clinicians explain to their patients the risks of these procedures, what complications he's more aware of today than he was then, and how he became more aware of those complications or their incidence rates.
MR. MYERS: You said from first started and then you said from his letter and then you said today.
MR. McCRARY: Okay.
MR. MYERS: I'm not sure if I understand the time period that you're asking.
MR. McCRARY: We can go from his letter. How about that?
MR. MYERS: Okay. I just, I just think the time --
MR. McCRARY: From when he started --
MR. MYERS: I just think the time period should be

Page 23

clear in this question.
MR. PICHE: Do you understand the question?
THE WITNESS: Yes, why don't you just repeat it in terms of what you're asking me in the time frame.
(BY MR. McCRARY) Q. Sure. And I thought we were on a good track.
And I thought what you told me is from when you first started using pelvic mesh when you were training and a new physician until you wrote or helped draft the response to the FDA notification letter, I thought you told me that you weren't necessarily more aware of complications but maybe incidence rates. Is that accurate?
A. That's accurate. And I think that with any new products we don't know the incidence until the product has been out for a long time and studied over a number of years because many complications are not apparent in the first few months or a year after surgery.
Maybe there's some delayed complications, so the longer there's followup then people become more aware of the true incidence.
Q. Is it your understanding that -- let's just say Boston Scientific, since that's what we're here about today, is it your understanding that Boston Scientific did any clinical testing on any of their pelvic meshes before they were released for marketing?

Page 24

MR. MYERS: Objection, form.
A. I'm not familiar with what Boston Scientific did, you know, premarket. I wasn't involved in any of that.
I could assume that they did what the FDA asked them to do and what was required at the time.
(BY MR. McCRARY) Q. And what's your understanding of what is required under the 510(k) process?
A. I understand the 510(k) process involves showing that your device is at least equivalent to the predicate device.
Q. Do you have any idea what pelvic device, what pelvic mesh devices were predicated upon?
A. Well, the majority of them were predicated on TVT, which was predicated on hernia mesh.
Q. Okay. How did you learn how to implant pelvic mesh?
A. I learned as most physicians learn, in their residency and in their fellowship, from their mentors. And Dr. George Webster was my fellowship director, and he taught me. And Dr. Wen Yap was someone I worked with a lot as a resident. And he was involved in instructing me.
Then as a physician in my practice, when we make small changes in our practice, maybe going from one incontinence procedure to another, we can make that change usually on our own or with the help of a video or a course

Page 25

that we might go to; that we become more familiar reading articles, reviewing the literature, looking at the information for users that, you know, the product company shares with you.
So that's how I would do it.
Q. Okay.
A. That's how I have done it.
Q. So you learned essentially through both reading materials that were provided to you, and also through your residency. Is that accurate?
A. And fellowship.
Q. And fellowship? Did you ever attend any training sessions sponsored by one of the device companies?
A. I have.
Q. And which, do you remember what company it was?
A. With Ethicon.
Q. Okay. And that was for the TVT?
A. That was for Prolift. I had learned how to do TVT as a resident. I didn't feel I needed any additional instruction on that product.
But I never used the transvaginal mesh kits in my residency or fellowship as they weren't available then. They came to market in 2004, two years after I finished my fellowship.
So I went to watch Dennis Miller in Milwaukee, who

Page 26

is a personal friend and watched him do those cases over the course of a day. And went to cadaver lab and was able to learn how to use the devices.

Q. Okay. I only have a couple hours with you, so I do want to talk about Amber's case.

Did you review the clinic notes that you have on Amber last night?

A. Yes.

Q. And I want to go through your chart specifically. But are you able to tell us a little bit about her history regarding her incontinence and treatment thereof before she saw you?

A. I know what's in the record. And I understand the surgery that she had with Dr. Davis. So I'm familiar with her care starting in around January 2011.

Q. Okay. And have you seen Dr. Davis' operative note?

A. I have.

Q. And did you have any comments as to her technique?

A. Dr. Davis performed the Lynx procedure on February 28, 2011. And I read the operative report. And it looks like she followed the usual protocol.

She mentioned where she made the skin punctures two centimeters lateral from the midline, which is recommended by the manufacturer. The Lynx is a product that's passed from

Page 27

the top down we like to say. And it's a mesh sling.

And it looks like she didn't encounter any complications during the case. She didn't have any significant bleeding; there was no injury to the urinary tract; there was no injury to the vaginal wall.

She performed cystoscopy when she completed the implantation, and didn't see any problems with the location of the mesh. And then performed her wound closure.

So it's not a very long operative report; less than a page. And it looked like a relatively straightforward case.

Q. And would the cystoscopy that Dr. Davis performed at the conclusion of the procedure have revealed any cuts or lesions on the urethra had there been any?

A. I would say for the most part it should.

Q. Okay. Is that part of why a cystoscopy is performed at the conclusion of these procedures?

A. Yes. I think cystoscopy is something that's considered mandatory on all retropubic midurethral slings.

If you look at the information that the manufacturer shares and also the recommendations from the American Urologic Association or AUGS or SUFU, everyone considers a cystoscopy to be an integral part of the procedure for retropubic tapes.

Q. And we talked to Dr. Davis about her care of

Page 28

Ms. Comer. And she mentioned that when she is implanting a sling, in order to leave the right amount of tension, she uses a type of scissor to place between the mesh and the midurethra.

Are you familiar with that technique?

A. I haven't read Dr. Davis' deposition so I'm not sure what she did to tension. She mentions in her operative report that she tensioned the Lynx sling. But there's no detail on how she tensioned it, so I can't comment on the scissors technique.

I can tell you how I tension it, but I don't know how she tensions it.

Q. How do you tension it?

A. I use a No. 10 Hegar, and I place that between the mesh and the urethra. The Hegar is a dilator. Think of it like about the size of the yellow highlighter there. And so it's just a spacer if you will.

So most physicians will use some kind of spacing so that it leaves some space between the mesh and the urethra. Some use their finger, some use a dilator, some use scissors, others use their forceps, so some sort of device to allow some space to prevent overtensioning.

Q. And so in her op report she said, "A curved Mayo scissors was used as a tensioning guide beneath the urethra."

Page 29

A. Do you have the operative report?

Q. Yes, I do, and I'll actually go ahead and mark it as Exhibit 3, just for ease of reference here.

(Exhibit 3 marked for identification.)

Q. Unfortunately this one's a little highlighted, but --

A. So I didn't see that in the operative report when I read that last night. So I'm corrected in saying that towards the end of the paragraph, "A curved Mayo scissors was used as a tensioning guide between the urethra and the blue circle was cut freeing the polyvinyl sleeve."

So she does mention how she tensioned the sling.

Q. And is that an appropriate technique?

A. Yes, I think that's an appropriate technique, yes.

Q. Okay. And how did Ms. Comer do postoperatively?

A. She had her catheter removed a few days later. And was having difficulties emptying her bladder, so she had to learn how to do self-catheterization.

So she had what we'd consider bladder incomplete emptying, meaning that she was only urinating partly. And the other part she'd have to empty with a catheter.

Q. And if you were the surgeon on this case, and your patient came back with that, with those symptoms, what would that mean to you?

A. Well, it would cause some concern. Typically

Page 30

patients are voiding normally by seven days. I would probably include maybe 80 percent of patients.

I would say 90 percent of patients are voiding by a month. And if say more than three months goes by and the patient is not voiding completely, then I'm concerned that the sling might need to be loosened.

I don't tend to loosen it before three months because there's often other variables that could be accounting for their incomplete emptying and it's not necessarily related to the sling tension.

So bladder incomplete emptying has a variety of causes, and so I like to rule out the other causes before I would have to take someone back to surgery.

Q. And is that why you wait the full three months, to try to help rule out other causes?

A. Typically for two reasons. One would be to allow other causes to go away. So if someone has a large amount of postoperative pain and they're taking narcotics, maybe their pelvic floor is very tense. They might not be able to void for that reason.

If they've had a concomitant hysterectomy or prolapse surgery like this patient did, there may be swelling or blood that's making the mesh artificially tighter than it is. And once the swelling or the bleeding, the hematoma resolves, the tension would be appropriate.

Page 31

So I like to let all those perioperative events resolve. And if at three months they're completely recovered and there's no other explanation for the retention, then generally I would evaluate them at that point with an exam.

Sometimes I would do cystoscopy or urodynamics, although not in all cases. And then I would discuss with them the risk and benefits of what we call a sling lysis.

Q. Okay. And we'll talk a little bit about that.

I think what you said, and correct me if I'm wrong, is that approximately 80 percent of your patients are voiding normally postoperatively after say a week.

And I think you then said, of the 20 percent that aren't voiding normally after a week, 10 percent of them will be voiding normally after three months. Is that accurate?

A. Yes, that's accurate, somewhere in around one to three months.

Q. Okay.

A. I think I said one month.

Q. So then that last 10 percent, is that a figure that's -- that accurately describes the percentage of people who have voiding difficulty after a sling implantation?

A. That is, that's my own clinical experience. I'm not aware of any studies where people have a timeline showing the percentages of people that are voiding by such and such a

Page 32

date. I don't think that publication exists, or if it does I'm not familiar with that publication. But I think those are the ranges.

But I could easily say that if someone's not voiding by three months most physicians have concern at that point that the patient's not going to void naturally unless there's some intervention.

Q. Okay. And you see that clinically in approximately 10 percent of your patients?

A. I probably see it in a little less than 10 percent. Ten percent, maybe five percent. I'd have to look at my exact numbers. But do I have patients that I have to loosen their mesh on? Yes.

Q. And do you implant mesh slings at the same tension in all your patients?

A. No. I adjust the tension to the patient. I try to personalize the care to that patient. It just depends on what their needs are and what their risk-benefit tolerance is.

Q. So I guess like hypermobility of someone's bladder neck may be a reason that you'd use more tension?

A. Probably less tension.

Q. Okay, all right. So Ms. Comer came in. She had her urethra -- I mean her catheter removed. And she was having some voiding issues, right?

Page 33

A. She was.

Q. And was she then given some time to try to let those issues clear up?

A. Yes. Dr. Davis took appropriate measures. She taught her self-catheterization. And I believe she extended her disability during that time.

She worked with her primary care physician to try to get Amber through those few months. But eventually things didn't resolve, and she took her back to surgery in April, about three months later.

Q. Okay. And have you read that operative note?

A. Yes. I read the operative report of Dr. Davis from April 8, 2011.

Q. I've got it here. I'm going to mark it as Exhibit 4, just so you can take a look at it if you want to. You don't have to certainly.

(Exhibit 4 marked for identification.)

A. So this is an operative report from the University of Colorado Hospital. Karlotta Davis is the author of the report. Amber Comer is the patient. The date's April 8, 2011. Her assistant was a resident physician.

There is a paragraph on the history of the patient. The preoperative diagnosis, urinary retention, meaning the patient cannot urinate.

The operation, sling takedown, which is also known

Page 34

as sling lysis. No. 2, urethrolysis and urethrotomy repair. So there was an opening in the urethra that was repaired. And then she did a cystoscopy also.

She has a description of what the anatomic findings were during the procedure. Then there's a narrative of the report. Blood loss is mentioned. The usual stuff.

Q. Okay. So Ms. Comer was having difficulties voiding. And since the problems did not resolve after a month I think it was, they decided to do a sling takedown or a lysis as you described it. Right?

A. Three months.

Q. Okay, three months.

And when you perform a sling lysis, do you, how does it, how is that performed?

A. Do you want me to mention how I perform it or how Dr. Davis performed it?

Q. Let's talk about how Dr. Davis did it.

A. So Dr. Davis said that she was able to identify the mesh using a nerve hook, which is a sharp instrument that can catch the mesh and identify it. The mesh integrates very well with the natural tissue, so sometimes it's hard to discern from the native tissue.

And then when she located that she used a small right angle clamp to dissect underneath the mesh, between the mesh and the urethra. And then when she was able to do that,

Page 35

she excised she mentioned 1.5 centimeters of the mesh.

Q. Okay. And at the conclusion of this procedure or I guess during the procedure she notices a, she describes it as a urethrolysis or urethrotomy?

A. Yes. Urethrotomy means that there would be an opening in the urethra or a hole in the urethra. And it looks like that occurred during the procedure.

And she recognized that and repaired that in two layers. And then she left a Foley catheter in afterwards to allow the urethra to heal properly over the catheter.

Q. And I just want to clarify real quickly. You said, when you said that occurred during the procedure, you're not talking that the urethrotomy occurred during the procedure, but the repair thereof, right?

MR. MYERS: Objection to form.

A. I'm not sure what happened, you know, during the surgery, whether the urethrotomy occurred during the procedure or before the procedure.

She says, "When I placed the right angle...a urethrotomy was immediately identified." So she identified it during the procedure, but she doesn't mention if it occurred during the procedure or it had occurred before the procedure.

(BY MR. McCRARY) Q. Okay.

A. So I don't know the answer to that. I'm sure Dr. Davis knows the answer to that.

Page 36

Q. Okay. So at the conclusion of this procedure, is it your understanding that Ms. Comer followed up with Dr. Davis several times?

A. She did, yes, and Dr. Davis saw her back for her postoperative followup.

Q. Okay. And can you just walk us through that follow up and sort of give us the run down how Ms. Comer went from seeing Davis to seeing you?

A. After the surgery with Dr. Davis, I believe Amber eventually healed up but was still having some issues with urethral pain and some slight incontinence.

And I don't know if Amber requested a second opinion or if Dr. Davis recommended that Amber see me, but I began following Amber in August of 2011.

Q. Okay. And I'm going to mark as the next exhibit my, my copy of your records. And feel free to use your computer, as I'm sure you're probably more comfortable with that.

But if you -- you know, I just want to mark these just for the sake of completeness.

MR. McCRARY: Andrew, I have a copy for you too.

(Exhibit 5 marked for identification.)

(BY MR. McCRARY) Q. I just want you to walk me through your treatment of Ms. Comer.

A. So I first saw Amber Comer on August 26, 2001.

Page 37

Q. Doctor, let me stop you real quick. I'm sorry.

Do you, sitting here today, know who Amber Comer is?

A. Yes, absolutely.

Q. Okay.

A. So Amber Comer, I can see there's a note here that I completed on this patient. Looking for the exact date. But I believe it was around August.

And she states that her urethra hurts every time she caths. She was denying any vaginal discharge or bleeding. She was having significant bladder spasms.

And I decided to do cystoscopy. And we did the cystoscopy on August 26 --

Q. Okay.

A. -- 2011. And I noticed during that time that I had some concerns that the mesh was very close to the urethra, if not in the urethra.

Q. And you determined that based on the cystoscopy?

A. Yes. I mention that -- I said that the mesh was not in the actual lumen, but I can see the mesh in the wall of the urethra.

So the Boston Scientific mesh is a blue mesh. And you can see that, you know, through structure. So you can see, you know, I would say you ordinarily shouldn't see it when you do a cystoscopy.

Page 38

The fact that you saw it would imply that it's maybe within the wall of the urethra, but not all the way perforating into the lumen of the urethra.
Q. Okay. So what were your concerns after your cystoscopy?
A. My concerns was that the mesh was not in the expected position, and that could be causing Amber her symptoms.
Q. Okay. And just so we're on the same page, are you looking at the 8-26, 2011 note?
A. I'm looking at that note. I think what you handed me here is not maybe in chronological order. Maybe it's in reverse chronological order.
Q. It is and that's just how they were produced to us.
So is the note you're looking at the one that says, under Plan, "I reviewed my experience with over 100 mesh complications"?
A. Yes.
Q. Okay. And I want to talk about that for a minute.
So "100 mesh complications including 20 urinary tract erosions in the last five years." So 100 complications over five years is 20 a year, right?
A. These are very approximate numbers, Sean.
Q. No, I understand that.
A. You know, I know what my recent numbers are. I

Page 39

don't know what the exact number would have been in 2011. So I'm paraphrasing my experience there.
But I knew that I had dealt with a significant number of complications. So I usually put that at the beginning of my plan so the patient and the referring physicians are comfortable with me making the statements that I make.
Q. Okay. And so in making that statement, are you then stating that you think you've got a case of a mesh complication here?
A. I have a complication, yes, related to mesh. It's difficult, you know, to phrase it accurately. But you have a patient who has a complication, and this patient has mesh in them.
So I'm not implying that the mesh caused the complication but, you know, they have those two things coexisting: they have mesh and they have a complication. And that's how we look at the patient. That's how we think of the patient.
Q. Okay. And I note or I see in that sentence there that you specifically state "100 mesh complications," and then you have a subset "including 20 urinary tract erosions."
And so basically what I'm wondering is, did you think this was a urinary tract erosion at that time?

Page 40

A. That's how I thought of it, yes.
So if the mesh is inside the urethra or what we would call an impending perforation within the wall of the urethra just under the mucosa, then I would consider that a urethral erosion. That's the term we used in 2011.
Now, the correct terminology is urethral perforation according to the International Continence Society. So if I use those words interchangeably, urethral perforation, urethral erosion, that's the same problem, that's the same entity.
Q. And can you describe in layman's term what that problem means physiologically?
A. It means that -- the word "perforation" means that there's a hole in the wall of the viscous. And you name what organ it is, so it's the urethra. And you might use a qualifier like mesh or suture to say what's perforating.
So if you say urethral mesh perforation you have mesh causing, or a hole in the urethra involving mesh. You might say suture urethral perforation or bladder or rectal, or whatever organ it is.
Q. Okay. And is this erosion that you saw, or perforation, is that the same hole that Dr. Davis saw during her second surgery with Ms. Comer?
A. More than likely.
Q. And so Dr. Davis' second surgery with Ms. Comer was

Page 41

a couple months out from the implant surgery. Is it possible for mesh to erode that quickly?
A. You have to repeat the question.
Q. So Dr. Davis initially did surgery on Ms. Comer. And postsurgically Ms. Comer wasn't voiding properly, so they went in to do a sling takedown. And Dr. Davis notes a hole in Ms. Comer's urethra, right?
A. Yes.
Q. Okay. My question is, is it possible that mesh could erode that quickly?
A. We see -- mesh perforations could be any time. Can be from the day after surgery, the day of surgery up until, you know, as long as the patients are followed.
The article that we published in International Urogynecology, the typical time frame was within one year. But we had seen some that had occurred as late as three and a half years after their implantation, some as early as, you know, just a few weeks.
The word "erosion" has meaning, and there's a lot of implications to that word. So we've gotten away from using that word because scientifically it means something different than the word "perforation."
Q. And you mentioned a minute ago that perforation and erosion, at least as far as you're concerned, are interchangeable. But to me, perforation just means that

Page 42

something's basically poking a hole in something else.
Is that your understanding as well?
MR. MYERS: Objection, form.
A. No. It's a long conversation to try to explain the differences between those two words. But I think perforation is a more generic term. It doesn't imply causation.
So think of like perforation as being a department store, and erosion is Wal-Mart or Target or something else. So, you know, the perforation is the big term, and then there's different things that can lead to perforation.
(BY MR. McCRARY) Q. Okay. So in your note on 8-26-11, is it safe to say that you described it, Ms. Comer's problem, as an erosion.
A. I did because that was the accepted terminology at the time as described by the International Continence Society. So I think it's important for physicians to use the correct terminology.
In and around 2012-2013, there was a landmark article that the ICS published on terminology and a staging system for mesh complications. So since then many of us have tried to classify these using that classification, and speak of them in that respect.
But, you know, the word erosion is going to persist for a long time. But I hesitate to use that, although I don't always speak properly so I sometimes do use the word

Page 43

erosion just because people are more familiar with the term.
Q. So --
A. But it's really like using slang.
Q. Okay. So sitting here today, would you describe this injury as a perforation and not an erosion?
A. Today I would. Then I called it an erosion because that's what everybody called it.
Q. Okay.
A. Now in 2014 I would say probably half of the people would use the word perforation, half are still using the word erosion.
Q. Okay. And what options did you discuss with Amber about her perforation?
A. Well, I discussed taking the mesh out and repairing the urinary tract, versus taking all of the mesh out and repairing the urinary tract and then placing a new sling using biological material.
Q. And I assume then that you discussed the plusses and minuses of each of those options with Amber at that time.
A. I did.
Q. And did you have a preference on which option might be best for her?
A. I had preferred the more extensive approach at that time in efforts to try to resolve the problem in a definitive manner.

Page 44

It is a more invasive approach so, you know, I hesitate in doing that. But seeing that she's already had one surgery after her initial mesh implantation I tend to take the more extensive approach in those patients.
Q. Is that because you feel that those patients are at a higher risk of having another complication?
A. No.
Q. So then why is it that you chose the more complex procedure?
A. I think at that point patients are willing to accept more risk and a more invasive approach.
Early on when there's issues after surgery we always try to take a least invasive approach in order to try to hasten the recovery. And if we see that that works then great, they recover faster.
If we see that that's not working then we have to go to, you know, plan B and use a more extensive approach.
Q. Okay. And you also gave her some literature at this visit, right?
A. Yes. I try to share with my patients as much information as I have available. Some of the literature is stuff I prepared. Some is just from the scientific literature if it's, you know, an article I feel might be useful.
Q. And so why did you think the Ridgeway article was useful for her?

Page 45

A. The Ridgeway article, you know, was one of the first articles in the scientific literature describing some of the techniques for mesh excision. That article did speak specifically about complications from mesh prolapse kits, which is not what Amber had, but I think a lot of the pictures in that article, there's very well-done color photos, and it just shows the technique that they use at the Cleveland Clinic.
Some of my techniques are similar to that, so I think that just helps the patient conceptualize what you're going to do at the time of surgery.
Q. Okay.
A. And Dr. Ridgeway and their colleagues are very well respected, you know, surgeons. And so, you know, I try to select articles that are contemporary from big centers, from well respected centers.
Q. Then it looks like you also gave her a copy of the AUA update that you helped draft?
A. Yes.
Q. And why did you decide to give that to her?
A. I like patients to know that they're not alone in this problem. A lot of times patients feel very unfortunate and they feel, you know, Why did this happen to me?
And I think it helps them understand the magnitude

Page 46

of the problem; that these problems do exist, and that there's well developed algorithms for how to manage that.

I think it gives the patient a level of confidence when they're going into surgery with their surgeon to understand that their surgeon understands the breadth of the disease and how to best manage that.

And I think especially if you've written that article personally, that gives them a lot of confidence in you as the surgeon, and so they're going to be more comfortable with you managing their issues.

So a large majority of my patients, you know, have had surgery with other physicians. And at some point they develop some uncertainty in the medical system, and they, they lose a little bit of faith. And so this is a way of trying to regain their trust by educating them.

Q. Do you have any idea why this occurred in Ms. Comer?

A. I don't.

Q. No? No, you don't even, you have no idea?

A. I have ideas generically how this happens, Sean. But I don't know why it happened to Amber. I don't think anybody really knows, you know.

I mentioned that in my AUA update and others have written on it that we understand that there's a problem and there's some hypothetical causes that we all think could be

Page 47

problematic. But I don't know it was putative in this case.

Q. And so you said that you have some opinions, but you don't know definitively why this happened to her.

What are some of your opinions as to why this may happen generally?

A. In all patients?

Q. Um-hum.

A. Well, you know, we've written about that. I think that if you just look at mesh perforation to the lower urinary tract in general, including mesh kits, if there was an injury to the urinary tract at the time of implantation that's probably the most significant event.

And if that was recognized and repaired, that's still a potential risk. Some would consider avoiding the procedure.

If you had an unrecognized injury, that certainly would be an issue. So that maybe there was a perforation that was created at the time of surgery so the mesh is in the urethra right from the day of implantation.

If the mesh is tunneled within the wall of the organ, so in the wall of the bladder or the wall of the urethra, then it would maybe eventually enter into the lumen. So that's not erosion at that point; that's more an iatrogenic phenomena.

I've had some theories that I've been developing in

Page 48

the last few years about mesh infection, and that infection created an inflammatory process, and that inflammatory process can eventually lead to the mesh perforating into the organ. That's just speaking about mesh in general.

If you look at tapes, most people would consider the most likely cause is an undue amount of tension on the mesh. And if the mesh has a lot of tension, then the mesh can perforate the urethra.

So, you know, that's the understanding we have. But unless you did the original surgery, unless you assisted in that surgery we don't, you know, really know what happened.

I read Dr. Davis' notes. I know there wasn't a perforation to the urinary tract. She did a cystoscopy. I know there wasn't a perforation that happened and she repaired it. So those two things probably aren't problematic.

But we don't know if it was tunnelled in the wall of the urethra. We don't know if it was from tension. We don't know if it was from infection.

So, I mean, there is some potential causes. But I can't say for certain which one of those things was the reason in this case.

Q. Okay. And along those lines there is a document I want to show you. And after I give it to you, we're going

Page 49

to go off the record for a minute so you have a minute to just take a look at it.

(Exhibit 6 marked for identification.)

MR. McCRARY: Let's go off the record.

THE VIDEOGRAPHER: Off the record at 8:17.

(Discussion off the record.)

THE VIDEOGRAPHER: Back on the record at 8:26.

(BY MR. McCRARY) Q. All right, Doctor. Before the break we marked Exhibit 6, which is an abstract article by Dr. Vladimir Iakovlev. And it doesn't say it on here, but I'll warranty that this abstract was accepted for oral presentation at an international pathology society.

And did you have a chance to review this over the break?

A. Very briefly.

Q. If you need to get that we can go off the record.

A. No, that's fine.

Q. All right. So Doctor, basically the reason I wanted to show you this was to ask you, have you ever had pathology performed on any of the explants that you've done?

A. Yes.

Q. And this article has some unique findings, specifically things like nerve ingrowth, polypropylene degradation.

Page 50

Have you ever seen evidence of either of those things in your practice?

MR. MYERS: Objection to form.

A. I'm not familiar with this article at all, Sean. I mean, I have only had a few minutes to really review. So I'm not going to comment on this article.

(BY MR. McCRARY) Q. Okay. So you have no opinions one way or another?

A. No. This article's not even published. It doesn't say what journal it's in. It doesn't say what year. It says, Accepted abstract. It's not peer reviewed as far as I know. So I'm not going to make any comment on this article.

If you want to ask me about pathology on Amber, I'm happy to ask -- answer questions. I did look at the pathology reports for Amber Comer.

Q. Okay. Let's talk about that.

You looked at pathology for Ms. Comer. And I assume that the pathology was done on the sling that you took down and removed?

A. There was the pathology from Dr. Davis' surgery I guess on April 11, and then another pathology report from the surgery I did. And that report was dated September 8 I guess when it was completed, but that's from surgery on September 6.

Q. Okay. And were there any significant findings in

Page 51

either of the pathologies that were performed either after Dr. Davis' surgery or after yours?

A. The April 2011 surgery, Dr. Davis' surgery was for gross examination. It mentions that there's skeletal muscle and fibroconnective tissue, negative for inflammation, no other abnormality.

That's a typical report that we receive at the University of Colorado Hospital on mesh excisions that happened early. I would consider this early.

Mesh excisions that come later tend to show some inflammation. On the September report it said, "Foreign material with minimal chronic inflammation," so there was some inflammation, but it was considered minimal.

That's about the extent of the pathological analysis that -- that we received from our pathological department.

Q. Is the lack of inflammation significant in any way clinically?

A. I think this is a very new science so we don't really understand how to interpret these pathology reports. I don't think pathologists have any standards on how to prepare the reports, and urologists, urogynecologists are not familiar with how to interpret the reports.

We send the reports because they're often requested by the Plaintiff's attorneys. Many of these patients have

Page 52

already -- have an attorney before their explant surgery, and we're asked to send that specimen. So we send that because we're asked to do that.

And we are trying to learn from this. I've looked at the microbiology of meshes here at the University of Colorado, but I've never looked at the pathology; I haven't organized any kind of retrospective review in those regards.

Q. So when you say you've looked at the microbiology, does that mean you've studied things like tissue ingrowth?

A. Tissue ingrowth would be considered more under the realm of pathology. Microbiology would be specifically looking at organisms we could possibly culture from the mesh.

Q. Have you found evidence of bacteria or other organisms in meshes that you've studied?

A. Yes.

Q. Do you believe that the way that the particular type of mesh is woven has something to do with the presence of bacteria in the mesh?

A. I'm not going to comment on that. All I can say is that I've seen bacteria in some of the meshes that we've explanted. I can tell you what those organisms are.

How they end up there I don't know, and whether that's related to the designs of meshes, that's something a materials scientist might know. But I'm not familiar with that.

Page 53

Q. Could it be related to the design of the meshes?

MR. MYERS: Objection to form.

A. I don't know the answer to that.

(BY MR. McCRARY) Q. Okay. I just want to show you. I'm going to mark Exhibit 7. I just want to know if you've ever read this.

(Exhibit 7 marked for identification.)

A. I don't believe I've read this specific publication. I am familiar with Dr. Ostergard and his work. But I don't think I've read this publication.

Q. And the reason I ask is because I want to know your opinion on something that he talks about on the third page of this thing.

I wish we had more time. But since we're so limited I'm just going to specifically point you to the part I'm interested in, which is page 964 on the right column. It's the second full paragraph that starts with "Given that polypropylene." Do you see that?

A. Yes.

Q. It says, "Given that polypropylene is not inert within the human body, that mesh shrinkage of up to 20 percent to 50 percent occurs, that large pore size is important for fibrous tissue ingrowth and mesh incorporation into host tissues, that surface area is directly related to subsequent infection, and that

Page 54

stiffness of the mesh is associated with complications, newer meshes should be designed with these factors in mind."

And I know there's a lot of different -- different topics in that sentence. And I just want to go through them one at a time and see whether or not you agree with each of them.

Do you agree that polypropylene is not inert in the human body?

A. I don't think any foreign body is truly inert.

Q. Do you agree that mesh shrinks in the human body?

A. Yes.

Q. Would you agree that it shrinks from 20 to 50 percent?

A. I think that's an overstatement. I would say less than 20 percent. And a lot of it depends on the design of the mesh. So there's a lot there, but I would say the shrinkage is somewhere between 5 and 20 percent.

Q. Can mesh shrinkage cause perforation?

A. Possibly.

Q. Could Ms. Comer's mesh have shrunk?

A. It could have, but I don't know if it did.

Q. Do you agree that large pore size is important for fibrous tissue ingrowth in mesh incorporation into host tissues?

Page 55

A. Yes. I believe large pore size is one of the, you know, favorable qualities of some of the newer designed meshes.

Large pore size would allow, you know, more native tissue and less foreign bodies, the idea to prevent fibrous scarring and bridging of the scars.

Q. And the next part is something we touched on a minute ago, that surface area is directly related to subsequent infection.

What do you think about that?

A. That gets to the phenomenon of mesh load. So the more mesh you put in, the more likely you could have an infection. So we try to use the least amount of mesh possible in order to get the best possible outcome.

So I'm not familiar with the phenomenon of surface area; I think of it more as a load in the amount of mesh that's being placed.

Q. And Doctor, have you seen evidence of mesh degradation in any of the mesh that you've explanted?

A. I touched on that earlier, Sean. This pathology report that we got on Amber, that's a typical report we see here at our hospital.

Our pathologists do not comment either way about degradation, so if it occurred I wouldn't be aware of it because our pathologists are not looking for that.

Page 56

Q. Okay. And we got off topic a little bit, and I apologize for that. It's time constraints.

We talked about the pathology that was done after Dr. Davis's surgery, and I think you mentioned pathology was done after your surgery as well.

What were the findings of that pathology?

A. So after Dr. Davis' surgery we mentioned that there was no inflammation. And they did see some fibroconnective tissue, skeletal muscle that's representative of the tissue surrounding the urethra. The skeletal muscle is probably not correct. I would have described that as smooth muscle.

With respect to the surgery I did, minimal chronic inflammation, so that's something that we touched on earlier. That's a pretty typical report.

Minimal chronic inflammation doesn't mean anything to me. If this patient had reoperative surgery for say incontinence without any mesh related events we may get that same exact report. So the fact that the report says chronic inflammation, that doesn't necessarily mean that there was a problem with the mesh.

Q. Okay. And so we left off talking about your August 26, 2011, visit with Ms. Comer. And you guys went over some options, potential options for her, and you gave her some literature.

I believe at that point you and Ms. Comer decided

Page 57

to do surgery; is that right?

A. Yes.

Q. And the surgery that you elected to do was a full sling takedown and implantation of a fascia graft?

A. What we'd say is a fascial graft, autologous rectus fascial graft.

On August -- on September 6, 2011, I removed her entire mesh sling. And we did that from an abdominal and vaginal approach. And we repaired an opening in the urethra.

And then we harvested tissue from her lower abdomen, autologous meaning her own, rectus from the rectus muscle fascia, white fibrous coating that coats muscle.

And that's what we call a classic or traditional procedure for stress incontinence. That is the procedure we often do commonly in these reoperative cases.

We also placed a suprapubic catheter at that time and a Foley catheter to try to put the urethra at rest, and allow the urethra the best chance of healing.

Q. Okay. So she had a catheter then coming out of her stomach at this point?

A. Her abdomen.

Q. Her abdomen?

A. Lower abdomen, and one coming out of the urethra.

Q. And the purpose of that was to avoid urine going through the urethra; is that right?

Page 58

A. That's right, so what we consider diverting the urine to put the urethra at rest.
Q. Okay. How difficult was it to remove the mesh in Ms. Comer?
A. It's a challenging surgery. I don't remember the surgery being any more difficult than the ordinary surgery. But in terms of surgery I do, it's definitely one of the more complicated ones we do in terms of removing mesh.
If it involves the urinary tract, that usually requires a urologist. Removing mesh in general is done by a wide variety of physicians, but if it involves the urinary tract, for the most part urologists will do that.
But it's a fairly technically demanding procedure. It takes somewhere on the order of three to four hours. We use magnification in doing that. It's not uncommon that someone would, you know, need a long hospital stay afterwards. It's a long recovery from an operation like this.
Q. And so at this point Amber's index surgery or implantation surgery was in late February 2011. We're now in September 2011.
Do you know if at any point in those eight months if she was able to urinate on her own without the assistance of a catheter?
A. She was urinating the entire time for the most

Page 59

part, but only partially, so she was using the catheter to empty the bladder more completely.
Q. And was that a daily thing?
A. A few times a day.
Q. Okay. So at no point in those eight months was she able to fully urinate on her own?
A. Yes.
Q. Okay. And when you do a fascia graft or a fascia sling like this, is it implanted similarly to how you would implant a synthetic sling?
A. No. It's done very differently.
Q. Okay. Can you explain that for me?
A. Well, it's a much more invasive procedure; it's a much more time consuming procedure. You don't have a product that's off the shelf that you can implant. You have to, you know, borrow from one area and put it in another so you have basically a donor site that needs to heal that creates a considerable amount of morbidity and abdominal pain afterwards.
We have to sew the graft into place because it doesn't grab on to the surrounding tissue the way the mesh would. Mesh has what we call the Velcro effect, so the mesh can be laid in there tension free and doesn't require any suturing.
And the tensioning on the tension free slings or

Page 60

TVT or Lynx is much more straightforward than an autologous sling.
Autologous slings fell out of favor for a lot of the reasons I mentioned earlier, because they're, it's a more time consuming procedure; it takes a greater amount of recovery; there's more pain associated with it, a hospital stay.
And then most importantly, the tensioning on those slings is much more challenging. It's something that I struggle with even to this day. And I've done more autologous slings than probably most people have.
But the incidence of retention and bladder incomplete emptying tends to be even higher with autologous slings than it does with TVT.
That was another big reason why people got away from doing them because it was at least a five to ten percent incidence of urinary retention and need for a sling takedown.
Q. Okay. And how is that different from the retention -- the percentage of patients with synthetic slings who had retention?
Because I thought earlier we said it was sort of in that ballpark.
A. I'd say it's lower. With synthetic slings it's probably somewhere between maybe one to three percent depending on the type of sling. If it's a transobturator

Page 61

sling or a mini-sling the incidence of retention is probably less than one percent.
With retropubic tapes it's around three percent. And then with the autologous slings it's somewhere on the order of five to ten percent. It may even be higher in reoperative cases.
You know, I have a conversation with the patient about the risks and benefits of the procedure, and see what their goals are.
You know, for some patients, in order for us to get them dry, there's going to need to be a considerable amount of tension, which might mean they have to catheterize occasionally and accept the catheter in the equation.
If they won't accept the catheter in the equation then we'll tension it looser, but they may not have 100 percent continence. They may be, you know mostly dry, but under more impact situations they may not be.
And so it's a very individualized treatment when you're doing slings.
Q. What are the benefits of a fascia sling over a synthetic?
A. The fascial sling generally is less likely to cause perforation. It can happen, but it's probably less than .1 percent. It's not going to be exposed through the vaginal wall; if it is, it would heal naturally.

Page 62

No one's going to have an allergic reaction to it or reject it, if you will. It's not go to become infected. So it's, it's a morbid procedure but it definitely has some unique advantages.

So I -- for my practice it accounts for about 50 percent of the slings I do.

Q. Okay. Let's go back to removal real quickly.

Did you ever receive any instruction from any medical device, mesh medical, mesh -- let me start over.

Did you ever receive any instruction from a mesh manufacturer about how to remove mesh if you face a complication?

A. No.

Q. Is there any information in any of the directions for use, that you're aware of, about how to remove a mesh if you have a complication?

A. No.

Q. How did you learn how to remove mesh?

A. Well, I learned how to lyse slings. So I've been cutting slings since I was a resident and a fellow. And early in my practice the majority of slings that we would cut or lyse would be biological slings because that's what was contemporary.

The surgical approach, the dissection, the exposure, all of that is virtually the same, so there's not

Page 63

anything very unique to lysing a mesh sling versus lysing a biological sling.

Q. Now, lysing a sling is different from a mesh removal, right?

A. Very different. Lyse would imply cutting an incision. So, you know, if you look at, you know, the simpler lyses is just exposing it and cutting it whether that's in the midline or lateral.

Then the next step beyond that would be a partial excision or what some would call partial explantation, partial resection. Resection, explantation, excision, those words are used interchangeably.

Dr. Davis excised one and a half centimeters of the mesh. A complete explantation or total explantation or complete mesh removal, you'll see me use those terms in my notes. That would imply we're taking all of the mesh out.

Q. Okay. And after you did this removal surgery on Ms. Comer, how did she do after that?

A. She continued to have issues. And she had continued issues with a need for a catheterization. We were eventually able to get her Foley catheter out and suprapubic catheter out but still had to return to doing self-catheterization.

And then events that required a reoperation from the surgery I did, so in February 2012 I took her back to the

Page 64

operating room to lyse the sling that I put in, the autologous sling.

Q. And so can you go through that procedure for me real quickly?

A. That was a one-hour outpatient procedure done under a general anesthetic. We did the procedure entirely through the vagina, vaginal incision.

We identified the sling. I cut the sling. After I cut the sling I identified a small perforation in the urethra. I believe that happened while I was cutting the sling, because the sling is somewhat embedded in the wall of the urethra.

And I recognized that immediately. I estimated that to be about a one-millimeter opening in the urethra. And I repaired that with sutures, and placed a catheter and allowed her to heal up.

And about a week later I removed her catheter. And I believe I only saw her one time after that.

Q. Okay. This hole or this urethral lesion that you saw, is it the same, is that the same area that we saw with Dr. Davis?

A. It's probably the same area we've been dealing with from the very beginning, you know. So where her mesh was originally implanted, where Dr. Davis resected it, where I then took the mesh out and then where I eventually cut my

Page 65

sling, all of those, it's all at the midurethra, which is the expected location of a mesh sling.

Midurethra, the urethra in the female is a very short organ. It's only three to four centimeters and so we're probably right in that center, one to one and a half centimeter area.

Q. Okay. How would you characterize this injury?

A. Which injury?

Q. This, this urethral hole or lesion that we've now seen for almost an entire year.

MR. MYERS: Objection to form.

MR. PICHE: Yes. I'm going to object to form too.

Could you, you said "this lesion." We've been talking about a number of different things. Could you be a little more specific?

(BY MR. McCRARY) Q. Well, there was, when she had her voiding problems after Dr. Davis' surgery, Dr. Davis went in and found a -- she described it as a hole in the urethra.

Then Ms. Comer got referred to you. And you described it as a urethral erosion. Then you did a fascia sling, had to lyse that, and you go in.

And now we see this lesion again and I asked you earlier if you thought it was the same thing that we were talking about from op report to op report, and I thought you said that it was.

Page 66

MR. MYERS: Objection. Completely misstates what he just said.
A. Yes. A lesion, people think of a lesion like a growth or a cancer or a tumor. This is certainly not a lesion. I wouldn't use the word "lesion."
(BY MR. McCRARY) Q. Okay. Well, I didn't mean it that way. I meant is sort of as a cut or a hole.
A. It's going to be hard for me at this point to go back and paraphrase everything that I've talked about for the last hour. If you're asking me to give a summary of what I've just said of the last hour, I don't --
Q. I'm not. I'm asking you to characterize her -- this injury that Ms. Comer has.
MR. MYERS: Objection, form.
A. She had a mesh sling that was placed. It was taken down by Dr. Davis, later removed by me. I placed an autologous sling that was too tight. I cut it. And the urethra eventually healed.
She had a subsequent MRI in 2013 that showed that the urethra had healed. And she had a difficult year. And, you know, she had four surgeries. The urethra, you know, had four surgeries on it.
That's all I can really say at this point.
(BY MR. McCRARY) Q. Okay. Having had four surgeries on her urethra, does that have any long-term

Page 67

effects?
MR. MYERS: Objection, form.
A. I haven't been following her long term, so I don't really know if it had any long-term effects on her.
I didn't -- I only saw her once after my last surgery. And I believe she went back to Dr. Davis for her care and Patricia Bolshoun, her primary care provider.
(BY MR. McCRARY) Q. And so you don't have any opinions as to how having your urethra operated on several times in a year could affect the performance of your urethra in the future?
MR. MYERS: Objection to form
A. I mean, you're getting into the hypothetical at this point, Sean. I don't have opinions on, you know, what that did to her urethra, no.
MR. McCRARY: Okay. I think I'll pass the witness.
MR. MYERS: Do you need to take a break?
THE WITNESS: I'd like to take a break at this point.
THE VIDEOGRAPHER: Going off the record at 8:53.
(Short break.)
THE VIDEOGRAPHER: Back on the record at 9:09.
CROSS-EXAMINATION
BY MR. MYERS
Q. Doctor, we met a little while ago. But you understand my name is Andrew Myers, and I represent Boston

Page 68

Scientific in this case, right?
A. Yes.
Q. And we've never met before today, right?
A. No.
Q. Okay. And you understand in this case that there's no claim against you or the clinic here, or any criticism of the care that you or anyone in the clinic provided, right?
A. "The clinic" meaning University of Colorado Hospital?
Q. Right, right. You or Dr. Davis or anyone else here for that matter.
A. I'm not aware if there's any lawsuits pending against Dr. Davis or University of Colorado Hospital. Maybe Sean could elaborate on that.
Q. Right.
A. But I don't know.
Q. Okay. Well, I just want to make sure that it's clear that this is a lawsuit between the Plaintiff and Boston Scientific. And the purpose here today is simply to get information from you.
And there's no intention here to criticize care or to lodge any claim against you, so I want to make sure you know that at the outset of the questions.
A. Okay. Thank you.

Page 69

Q. So anything I'm asking you, it's not with the intention to get at you in any way; it's just to get information about the care that was provided.
A. I understand.
Q. Okay. And I'd just like to ask you a little bit. There's this big litigation here. And if this case goes to trial it may go to trial here in Denver, it may be some-where else. And so it's possible that the people wouldn't know much about the university here or where you practice.
So if you'd talk a little bit about this clinic, because I know and you know that this is probably the top place in the Rocky Mountain region to go for medical care. But if you could just talk a little bit about where we're sitting today and where this is for a place for care for people in Colorado and the surrounding region.
A. You want me to talk about my own credentials or the hospital's credentials?
Q. Both, please.
A. Okay. Well, I mentioned at the beginning of the deposition that I'm the co-director of female pelvic medicine here. In that clinic Dr. Kathy Connell is the other co-director with me. She's a urogynecologist.
We have Dr. Karlotta Davis and Dr. Tyler Muffly. We're all partners in the sense that we all belong to University Physicians Incorporated, which is more than a

Page 70

thousand physicians. That is essentially the faculty for the medical school, University of Colorado.

And so I'm very familiar with Dr. Davis and Dr. Connell, Dr. Muffly. The four of us see patients in the same office space. And we collaborate regularly on patient care and on projects. And we have a long-term relationship.

University of Colorado Hospital, the School of Medicine has existed for at least 40 to 50 years. I don't know the exact date. But this campus, the Anschutz Medical Campus started to develop around 2000.

And when I came here in 2002 part of the campus was on 9th and Colorado and part here, and then over a 10-year period they transitioned completely to the Anschutz Medical Campus.

This campus is the biggest medical center in a five state region in terms of just looking at the physical size of the campus and the number of hospitals on one campus. So Children's Hospital's here, the University of Colorado Hospital, University of Colorado School of Medicine, pharmacy, dentistry, all the professional schools. There's a number of research buildings and research activity going on.

The University of Colorado Hospital has been ranked in the top 10 US World and News Reports. The division of urology, which I'm a member of, has been ranked in the top 40, recently we're ranked No. 35 in the country in urology.

Page 71

So I very strongly believe that we're a very strong medical school with a mission to serve citizens of this state and neighboring states. And we have an academic mission to also teach residents and fellows and medical students as well as the mission we have to our patients and the public.

Q. And focusing on you and Dr. Davis, because you're the two doctors from this clinic who were involved in treating Ms. Comer, my impression coming in is that you are two of the most respected doctors probably in Colorado, probably in this region of the country, in treating women's pelvic health.

Do you think that's a fair statement?

A. I do. Dr. Davis was just elected one of the top docs in 5280. I've been one of the top docs in Colorado Business Magazine. So, you know, we're certainly recognized by our colleagues in the community as well as at the university as being some of the top docs in this region.

Q. We talked about, I think you mentioned earlier today, women's pelvic health. Can you talk a little bit about what that entails?

A. Well, Women's Pelvic Health and Surgery is the name of our clinic. We chose that name, Dr. Connell and I, in order to be reflective of the various specialties that practice in that clinic.

So we have urologists, we have urogynecologists.

Page 72

All of our urologists and urogynecologists, the four of us that I mentioned, are all board certified in female pelvic medicine and surgery, which is one of the newer recognized specialties by the American Board of Medical Specialties.

There's only 35 or 40 medical specialties out there, and female pelvic medicine is the newest one, and so this is the second year that they've offered an exam and certification, so it's still a pretty new specialty. But that specialty consists of urologists and urogynecologists.

In our Female Pelvic Medicine and Health Clinic we have physical therapists, we have nurse practitioners, physician assistants, we have a variety of providers there to try to provide care for women with pelvic health problems that are benign problems.

We don't deal with cancer, but it predominantly centers around incontinence and prolapse.

Q. Are prolapse and incontinence serious problems in women's lives?

A. Absolutely.

Q. Why is that?

A. It steals from the quality of life that a woman would enjoy. So these ailments don't affect quantity of life but affect quality of life.

So people tend to not live as active a lifestyle. Incontinence especially can lead to social isolation. And it

Page 73

definitely affects the quality of life of women that suffer from these disorders.

Q. And focusing specifically on incontinence, because that's what Ms. Comer obviously was treated for, is that a problem that your patients find it important to have treated?

A. Yes.

Q. And is that a problem that they and you as their doctor feel it's important to have effective and safe treatments for?

A. Yes.

Q. And as you sit here today, what do you believe is the standard of care, or some people say the gold standard, for treatment of stress urinary incontinence?

MR. McCRARY: Object to form.

A. The standard of care for stress urinary incontinence?

(BY MR. MYERS) Q. Right.

A. That's a pretty wide-reaching, you know, topic of stress incontinence.

But most people would consider the midurethral sling an important treatment option for women. If you look at the statements from the American Urologic Association, AUA, or from SUFU, Society of Urodynamics and Female Urology, or from the AUGS, all of those professional

Page 74

societies have put out a public statement supporting the use of the midurethral sling as an important option, treatment option for stress urinary incontinence.

I personally try not to use the word "gold standard" because, you know, it's a word that means different things to different people.

Q. And it was discussed earlier that you were involved at one point in drafting a statement for the AUA concerning pelvic mesh. Do you recall the year that that was, that you drafted that statement?

A. Well, yes. We -- I know the exact year we -- we drafted it probably from '08 to '09, and it was published in 2010.

Q. Okay.

A. So usually a publication of that magnitude and that length takes a year or so to write.

Q. Okay. And I think you just mentioned that the current statement of the AUA is that the standard of care for treatment of stress urinary incontinence is a midurethral sling. Is that correct?

A. I don't know if it says standard of care. I don't know --

Q. Okay.

A. -- if you have the statement in front of you --

Q. I actually do have the statement. Let's look at it.

Page 75

A. I think we'd want to be careful about exactly what words they use.

But I know that they did put out a statement about supporting the use of it, and that they felt that it would be a disservice if there was any limitation on the use of a midurethral sling.

Q. So I marked that as Exhibit 8.

(Exhibit 8 marked for identification.)

Q. Which I believe is the statement you were referring to dated 2011 from the AUA, which is titled, "AUA Position Statement on the Use of Vaginal Mesh for the Surgical Treatment of Stress Urinary Incontinence."

A. Yes. It says the AUA -- it says, "The midurethral sling, mesh sling, is the most common surgery currently performed for SUI. "Extensive data exist to support the use of synthetic polypropylene mesh" midurethral "slings for...female SUI...minimal morbidity compared with alternative surgeries."

I absolutely agree with that statement.

"Advantages include shorter operative time/anesthetic need, reduced surgical pain, reduced hospitalization."

I believe I alluded to that earlier in the deposition.

"Mesh-related complications can occur following

Page 76

polypropylene mesh sling placement."

They rated this complication as acceptably low. So there is a recognized complication with any surgery. But the risk-benefit ratio is favorable.

"The AUA's opinion that any restriction on the use of synthetic polypropylene mesh suburethral slings would be a disservice to women."

So they go on and on in the statement. They say, "Synthetic slings are an appropriate treatment choice for women with stress incontinence." They do indicate intraoperative cystoscopy should be performed.

Then they talk about agreeing with the FDA that rigorous training is necessary; that people should be trained in specific techniques; be able to recognize and manage complications.

So I don't see anywhere in the statement where they use the word "gold standard."

Q. Right.

A. But this is a very strong endorsement of the midurethral sling.

Q. And I wanted to ask you first, because you were involved in the previous statement, if you had any involvement in the drafting of this position statement.

A. No. I'm an AUA member. I do sit on some committees, but I wasn't a member on the committee that

Page 77

drafted this statement.

Q. Okay. And this statement, I think it was published in November 2011. And you mentioned, for example, that it says cystoscopy should be performed during implantation.

And I believe you mentioned earlier that Dr. Davis did perform cystoscopy during the implantation with Ms. Comer's Lynx. Is that correct?

A. That's correct.

Q. Is there anything in this statement that you weren't well aware of at the time of the implantation for Ms. Comer in February of 2011?

A. When this statement came out, I read it thoroughly. And most of this was not new information for me, but it only confirmed how I approached this problem, and how I felt about this problem.

Q. So in other words, is it fair to say that you were aware of the potential for erosion or -- I'm blanking on the other term --

A. Perforation.

Q. -- or perforation, whichever term you want to use, at least in 2011, 2010, in that time period?

A. Yes.

Q. Okay. And is that something that you had discussed with Dr. Davis?

A. Discussed what?

Page 78

Q. Discussed the potential side effects or the potential I should say complications of sling surgeries.
A. Dr. Davis and I, you know, we've had conversations about slings and how we approach incontinence. It wasn't specific to Amber Comer's case.
Q. Right.
A. But sure, at some of our, you know, monthly meetings or sessions, you know, publications that we've done together, PowerPoint presentations, you know, presentations to the community, we'd have a very similar approach to incontinence.
Q. And for example, if we go back to 2010, were you teaching residents at that time about the implantation of midurethral slings?
A. Yes.
Q. And were you teaching them that erosion was a potential problem with the implantation of the midurethral sling?
A. Yes.
Q. Were you teaching them that dyspareunia was a potential problem with the implantation of the midurethral sling?
A. In 2010?
Q. Yes.
A. Yes.

Page 79

Q. And is that, is that something that was sort of common knowledge, and discussed here at the clinic, and just something that was commonly known?
A. At that time, 2010, yes.
Q. Okay.
A. I would say earlier, no.
Q. Okay. So I guess hard to say exactly the date that you knew it, but certainly by 2010 you think you knew that?
A. Yes. By 2008 when the FDA PHN.
Q. Okay, okay. So at least 2008 and after you certainly knew those potential complications could occur with implantation of a midurethral slings?
A. Which complication?
Q. Dyspareunia and erosion.
A. Yes.
Q. And that was something that you discussed with your colleagues like Dr. Davis and people you were training, and other people in the clinic?
A. Yes.
Q. Okay. Ms. Comer ever ask you any questions about her lawsuit?
A. No. I wasn't aware of this lawsuit until I received the notice of deposition.
Q. Okay. Did Plaintiff's counsel ask you any

Page 80

questions about the lawsuit?
A. No. We've never met or talked before today.
Q. Okay. Do you know if there was an attempt to speak with you? Or you simply had no contact before today?
A. I don't believe there was any contact or attempts at contact from Sean to me.
Q. Okay. Does stress incontinence usually improve without treatment?
A. Not ordinarily.
Q. And as a patient gets older, does it usually get better, or does it usually get worse?
A. If they had incontinence, you know, say that developed immediately postpartum, that may improve. And then they will usually reach a plateau where maybe they'd be fully recovered or only partly recovered.
And then often will return sometime around menopause and can degenerate. It can be a degenerative condition, yes.
Q. What are the treatment options for stress incontinence?
A. Well, typically we start out with what we call self-care or lifestyle changes to try to avoid the triggers. Try to urinate on a regular schedule, try to avoid caffeine and alcohol, and to perform what we call pelvic floor exercises, also known as Kegel exercises where the patient

Page 81

would tighten up the pelvic floor and do a certain number of repetitions, a certain number of sets per day.
And if those simple measures don't work, then working with a physical therapist can be considered an option where they'll do something more formal in terms of strengthening the pelvic floor with weights or cones or with biofeedback.
If those options aren't successful, there's certainly a number of surgical options one can consider.
Q. Do those conservative measures that you just discussed, do they usually work?
A. They can work. I don't know the exact percentages. But for milder degrees of incontinence, say someone's wearing a pad only occasionally or not at all, especially people that have birth trauma or maybe have some antecedent event that led up to the incontinence, they can have pretty significant recoveries.
But I would say for most patients that I see at least personally that have larger volumes of incontinence, generally they're ineffective.
Q. And looking at the patients who don't work with conservative treatment, what are the surgical options that are available?
A. Well, going from least invasive to most invasive we can do a transurethral bulking agent. That would be a

Page 82

product that we inject into the urethra to try to swell the urethra. That would be the least invasive option that I offer patients.

Some physicians would offer the Renessa procedure. It's not a procedure we have available here, but that would be a microwave therapy to treat the pubourethral ligament to try to change the architecture of that ligament to get it to tighten.

Beyond those therapies, one could consider the midurethral sling like the Lynx sling for instance. There's a variety of slings under that umbrella, the midurethral sling. There's mini-slings, transobturator slings, and retropubic slings. They're all mesh slings that are placed at the midurethra.

Beyond that, one can do what we call some of the more traditional procedures. Our native tissue procedures. You'll see those words used like the autologous rectus fascial sling.

You can also use other biological material from an animal, what we call a xenograft or from a cadaver, allograph, so you can do the same pubovaginal sling using those graft materials.

Lastly you can do what's called a needle suspension or colposuspension, which is a suture based repair where one would place sutures near the urethra and use that,

Page 83

to suspend the urethra to say the pubic bone or Coopers ligament.

Q. As of today, if you have a patient you have decided to operate on for stress urinary incontinence, what is the most common surgery that you perform?

A. I perform bulking agents about ten percent. I use the midurethral sling 40 percent, and autologous rectus fascial slings 40 percent.

Q. Okay. So those are about equal?

A. Yes. About 45, 45, 10, yes.

Q. And how do you decide between the midurethral sling and the autologous graft?

A. Most of what we call the index case -- the index case is a recognized terminology that the American Urologic Association uses when they describe their guidelines for management of a variety of conditions.

The index case is someone that, you know, is newer to the disease, hasn't had prior surgery, doesn't have any adverse features, we would offer them the midurethral sling.

Someone with adverse implantation features or someone that's had a negative experience with mesh, then we would favor an autologous rectus fascial sling.

Q. So is the reason that you're offering autologous rectus grafts to your patients because you see a lot of people who are not index cases?

Page 84

A. Absolutely. I would say the overwhelming majority of the patients I see have had at least one surgery; some women as many as five or six surgeries before I meet them.

The University practice is a very tertiary one. Mine is beyond that. I receive referrals not only from urologists but from other urogynecologists and specialists in female pelvic medicine.

So I didn't mention also the artificial urinary sphincter. I also offer that as a therapy. Bladder neck closure, even urinary diversion. So, you know, I offer the whole spectrum of surgeries.

Some of these we do so infrequent they're maybe not worth mentioning. But, you know, I have a very tertiary practice.

So the change in my practice patterns is something that we've written about and published on and presented on, but it may not be reflective of what happens in the community.

Q. So is it fair to say that you are receiving the more difficult cases?

A. Yes.

Q. Okay. And from what region do those cases come?

A. From about a 10- to 12-state area.

Q. Okay.

A. So from North Dakota to Texas, west to Montana and,

Page 85

you know, to -- north to Montana and west to Utah, Arizona, even Nevada and southern California.

Q. So anyone in that region who has had some sort of a problem previously with their treatment for stress urinary incontinence or pelvic organ prolapse may get referred to you?

A. Possibly. You know, I think because I -- I've written about this and I've talked a lot about it that -- and I've trained a number of physicians who have relocated in some of those areas that I might see patients from those particular areas.

And a lot of the patients we have here in Colorado they might spend the winter in Texas or Arizona or New Mexico and summers here, or vice versa. They might spend the winters here and the summers in Montana. And so some of those people, you know, have two homes.

And, you know, there's a -- the University practice is really growing pretty rapidly. We're close to the airport here. And so it's not uncommon that we see patients from out of state.

Q. Now, I recognize that Ms. Comer had obviously a number of complications. But if she came in today as an index patient, as you just described, would you offer her a midurethral sling?

A. Yes.

Page 86

Q. Okay. And would you have a preference as to which midurethral sling you offered her?
A. It would depend. There's some nuances of the index patient. And younger patients, patients that are very active, I like the support from the retropubic midurethral sling. I think that you can get a greater degree of support.
Certainly in today's medical-legal environment we're all migrating towards products that have been extremely well studied. And the midurethral sling in the retropubic location is the most widely studied when you compare it to transobturator and mini-slings.
And so for that reason I kind of migrated back to doing mostly retropubics. I did retropubics earlier in my practice, then obturator, then minis, and now it's mostly back to retropubics again.
Q. I think you mentioned earlier that you currently use either TVT -- I forget the specific -- TVT Secur --
A. TVT Exact.
Q. Okay. Or the Advantage Fit?
A. Yes.
Q. Are those the two midurethral slings that you use at this point?
A. Yes.
Q. Okay. I think you also mentioned that you've never used the Lynx device.

Page 87

A. I've never used the Lynx device.
Q. Is there a particular reason for that?
A. I was trained on the bottom to top approach as a resident with the classic TVT by Dr. Wen Yap. And so that was what I was most familiar with and just from my training, and the TVT being the most widely studied medical device in female pelvic medicine, I just felt very comfortable using that product.
The Lynx product or any of the top down products I have done like the SPARC for instance from American Medical Systems. But I've always felt more comfortable with the bottom to top approach.
Q. So fair to say that you don't necessarily have any problem or criticism of the Lynx? It's just not something you've ever used enough to -- or used or become comfortable with?
A. Correct. And we have both options available to our physicians at our hospital through the products committee. We usually try to have anywhere from two to four midurethral slings available depending on which providers we have on staff.
And so I don't have a problem with it, but I think, you know, people get good at what they do commonly, especially if you're teaching. I like to have the consistency of doing the same procedure over and over again.

Page 88

I think that allows me to teach it better, and allows our residents and fellows to learn better.
Q. Is there, to your knowledge, an appreciable difference in the mesh that's used in the Lynx compared compared to the products that you use in midurethral sling surgeries?
A. Are you asking me if Lynx is different than TVT Exact or the Advantage Fit?
Q. Either, any of them.
A. I'd have to look at the specifics. But I know they're all a monofilament knit and they have pretty similar mill size in terms of the fibers and the pore size. They are both surrounded with a plastic envelope. There's a trocar attached to it.
So I think overall they're pretty similar in design. I'm sure there's some slight differences between the kits. There has to be I would think for proprietary reasons.
Q. Let me ask the question this way. Looking specifically at the mesh, not the hooks or anything else that's used in the kit, but the mesh that's involved in Lynx or any other midurethral sling that's on the market, does it play into your clinical decision-making that there's some difference in this mesh or that mesh?
A. Yes. I, I mean, I highly consider what mesh I'm using. I don't think they're all the same.

Page 89

Q. Okay.
A. I mean, there's a classification of mesh, the Amid classification. So generally physicians, you know, since 2004 have been using a type 1 polypropylene type mesh. That's been the standard in terms of those that are using polypropylene mesh.
Q. Okay.
A. Or any synthetics.
Q. And do you have an understanding that that type of mesh is used in, for example, all the Boston Scientific midurethral slings?
A. I know that they use it for Advantage Fit and for Lynx. I can't -- I'm not familiar with all of the products.
Q. Okay.
A. But at least for those two products.
Q. Okay. Counsel earlier was asking you questions more generally about pelvic mesh.
Do you draw a distinction between mesh for stress urinary incontinence and mesh for pelvic organ prolapse?
A. The meshes are very similar but, you know, you have transvaginal mesh, which would include mesh for prolapse and mesh for midurethral slings. We mentioned earlier about mesh load. And certainly there's a lot less mesh implanted with a sling compared to a prolapse kit.
Q. Do you consider the potential for complications

Page 90

to be the same for a midurethral sling as for pelvic organ prolapse surgery if you use mesh?
A. The complications are the same, but the complications occur more commonly with the pelvic floor mesh kits, the prolapse kits. That's what the original FDA PHN centered more around, prolapse kits than midurethral slings.
Q. Okay. And if I remember correctly, I think you mentioned that you no longer use or don't use -- I'm not sure if you ever used transvaginal pelvic organ prolapse kits.
Is that correct?
A. I used the mesh prolapse kits, specifically Prolift, which is --
Q. Okay.
A. -- a product from Ethicon, and Elevate --
Q. Okay.
A. -- from American Medical Systems from 2004 to around 2000 and maybe 10 or 11. I would have to look at the exact date that I used the last kit.
But after the second FDA update, and then certainly when Ethicon stopped manufacturing Prolift, many of us stopped using the prolapse kits.
Q. And that's what I'm trying to get at is that whether you view that there was a difference there, that what FDA was saying and in your own view that there

Page 91

was a potential for adverse effects associated with pelvic organ prolapse kits that exceeded the potential if you treat with a midurethral sling?
MR. McCRARY: Object to form.
A. Can you repeat the question?
(BY MR. MYERS) Q. Do you believe that the incidence of adverse effects, of complications associated with pelvic organ prolapse kits is greater than with midurethral slings?
A. Yes. I believe the incidence of mesh complications is greater with prolapse kits than midurethral slings, yes.
Q. And is that why you made a distinction in your practice that you continue to frequently use a midurethral sling and you don't any longer use a pelvic organ prolapse kit?
A. It was a decision I made after reviewing the public health notifications, after looking at the statements from the professional societies, and reviewing the peer review literature.
There was a number of articles from Dr. Iglesias and others that stated that, you know, mesh in the anterior compartment for prolapse improved the subject -- the objective outcomes, meaning how the anatomy might have looked, but not the subjective outcome on how the patient

Page 92

feel -- felt.
So if the patient didn't have any significant benefits and had added risk, then why use it?
Q. Now, looking at use of midurethral slings, do you have an understanding that there is a risk with that surgery of postoperative pain, including dyspareunia?
A. Yes. I discuss that risk with patients.
Q. Okay. And is that a risk you've been aware of since at least 2008?
A. At least since 2008, yes.
Q. Is that a risk that would exist with any transvaginal surgery?
A. I would say it would be a risk with most transvaginal surgeries. I'm sure there's some minor procedures where it wouldn't be a risk.
Q. You mentioned earlier that if you have an index patient, a patient who's had no previous adverse experiences with mesh, the preference is to use mesh rather than an autologous graft.
Why is that?
A. I think what we mentioned in the AUA statement, that it's minimally invasive. Minimally invasive means that it's relatively straightforward to do, doesn't cause a great amount of pain or convalescence for the patient, quick recovery, brief surgery, outpatient, quick return to normal

Page 93

activity with minimal risk.
So those were all ideal characteristics that patients, you know, look forward to. And more importantly, has very high success rate in terms of resolution of the stress incontinence.
So there are a lot of minimally invasive procedures out there that, you know, are minimally invasive but not effective. I don't do those procedures. So I try to look for minimally invasive procedures that are also effective, so that -- that's the midurethral sling.
Q. And are there any effective procedures that you could offer a patient that are without any risks?
A. No.
Q. And are there any procedures you can offer your patients that have 100 percent chance of cure?
A. No.
Q. And you've been discussing today, you know, various, seems like you're pretty aware of, you know, there may be a five percent chance you're going to have to go back and revise this type of surgery or maybe a three percent here.
It sounds like you're pretty aware of if you offer various, if you offer this type, an autologous sling or a mesh sling, that there's a differential rate of different adverse outcomes let's say. Is that fair to say?

Page 94

MR. McCRARY: Object to the form.
A. Can you repeat the question?
(BY MR. MYERS) Q. Yes. I can ask it a lot better than that. It was a poorly worded question.
When you offer a patient either a midurethral sling or an autologous graft, is it fair to say that you are aware that there's a percentage of your patients who will not have a good outcome for that surgery?
A. Yes.
Q. And whatever that percent is, if it's five percent, if it's ten percent, is it also fair to say that you can't tell going in which patients will be in that five or ten percent?
A. There's some risk stratification that we do so we could identify people that are at risk. And so each patient's different.
But, you know, I really try to individualize things and look at all their potential risk factors and then offer them the best therapy that I feel is best for them and what their risk tolerance is. Everybody has different risk tolerance.
Q. Well, let's talk about a specific patient. Let's talk about Ms. Comer.
Obviously she's a patient who had a number of surgeries and did not have a successful outcome from the

Page 95

surgeries. And if I understand correctly, it's hard to tell exactly why her surgeries were not successful. Is that fair?
A. That's fair.
Q. Okay. And is it also true that it was impossible to tell going into her surgery that she would've been one, she was one of those people who was not going to have a good outcome?
A. Yes. There was no adverse implantation features, if that's what you're asking. Just looking at her generically, you know, compared to other patients, she was of the typical age that we offer this procedure on.
There was nothing to suggest that she would have an adverse outcome.
Q. And as a doctor, obviously what -- you really like to be able to identify the patients who aren't going to have good outcome for the surgery, and then you could just not operate on those patients, right? Or you could offer them something different?
A. Something different or counsel them differently and see if they're going to accept the risks.
So there's surgeries we do that we know there's a 40, 50 percent chance of having a complication.
Q. Right.
A. But if the patient's having enough suffering from that disease they're going to accept that risk.

Page 96

People that have, you know, less suffering are going to accept less risk.
Q. But at the same time, your practice as you described it to me is premised on the fact that people are coming from 15 different states or so who have all had an unexpected outcome that was not as good as their doctor hoped they would have had.
A. Not all of the patients. I mean, my practice is really two tier. We have patients like Amber that come through our system that are very similar to patients that doctors in the community see.
The University has five primary care sites, so certainly we see patients primarily. Most of those migrate toward urogynecology, Dr. Davis for instance.
But I do have a percentage of index cases I see, hence the 50 percent of patients that I do the midurethral sling on. Many of those are very straightforward index patients.
So we try to have a balance in the practice, you know, of both, of the whole spectrum of disease being a teaching program. And we have a fellowship program. It's important that we try to get those experiences available to all our trainees, and meet the demands not only of the patients in the neighboring states but the patients within our own community in Aurora and what we call University

Page 97

patients, patients that have primary care providers in the University practice.
Q. Let's go and let's look at your first visit with Ms. Comer again. And this is Exhibit 5. If you want, if you want to look at it on your computer that may be a lot easier.
A. This way I'll be assured that I have the visit that we're interested in.
Q. So this is a visit dated --
A. What date?
Q. 8-26, 2011.
A. Okay. I'm opening up that note right now. And I do have it in front of me.
Q. Okay. And so the first question I wanted to ask you about was Counsel pointed this out earlier that under "plan" you said you reviewed your experience with over 100 mesh complications, including 20 urinary tract erosions in the last five years.
I just want to clarify that statement with what we've just discussed. That's based on folks with problems from 15 different states, right?
A. Yes. That's a big catchment area. But, you know, if you look at the publication that I had in International Urogynecology, we looked at the number of urinary tract erosions that we managed. And I mentioned that three of them were my own.

Page 98

I had three patients that were my own patients in that study. And I had the other population I think was 21 patients in our study. The other 18 were someone else's patients. Many of them were from other parts of the region.

Q. So is three a better estimate for the number of patients you actually operated on yourself who then developed an erosion?

A. Yes. So in that publication I mentioned I did 600 midurethral slings in about an eight or ten year time period. After the PHN, physicians were asked to keep track of their data and go back and review their data. So I reviewed that personally.

And we published on that in that article. And I found three patients that I had personally implanted out of 600 that had a urethral erosion or urethral perforation from their mesh sling.

Q. So that is about .5 percent?

A. It's .5 percent, which is about what the incidence is that's reported. People report somewhere on the order of .2 to maybe .6 percent.

Q. And you find that .5 percent in your own experience to be an acceptable complication rate?

A. I'd like it to be zero, but I don't think it will ever be zero. I think it's acceptable. I continue to do the midurethral sling, so obviously I accept that complication as

Page 99

long as my patients are understanding of that risk.

Q. If you look down in the third paragraph it begins, "She prefers to have everything done at the same time."

A. Yes.

Q. Then the second sentence there says, "The primary disadvantage of the biological graft is that it would not have the same durability as a synthetic and has a slightly greater risk of causing post-op voiding dysfunction (retention, de novo, UUI)."

First of all, what does de novo UUI mean?

A. De novo meaning new onset. UUI, urinary urgency incontinence.

Q. Okay.

A. So that's a form of voiding dysfunction, retention, incomplete emptying. And de novo UUI can result from a sling being too tight.

Q. Okay.

(Discussion off the record.)

Q. And then the next sentence you say, "The positive would be it would not erode into the urinary tract or vaginal" -- you probably mean "or vaginal wall"?

A. Or, yes.

Q. So is that sort of what we've been discussing, that there's plusses and minuses of either type of graft?

A. That's correct.

Page 100

Q. Okay. And the positive of the mesh is that it's more durable and less likely to cause an obstruction. And the positive of the autologous graft is that it's less likely to cause erosion?

A. Correct.

Q. Okay. Is that something you would have discussed with Ms. Comer at the time?

A. Absolutely.

Q. And then in the next paragraph you discussed, you reviewed the risks with her?

A. Yes. And this is a quick summary. We have an actual informed consent form. So there's probably other risks that have been outlined in an informed consent. This is just a summary of all those risks.

Q. Okay.

A. But this is not the actual consent form; this is just more preoperative counseling.

Q. Okay. This says, for example, it says here the word "dyspareunia." And I think you and I know that that means pain with intercourse.

But it's, would you have used the word dyspareunia with her? Or would you have explained what that means?

A. I would have explained what it meant.

Q. Okay. So you would have explained to her that one of the potential risks of this surgery was that she'd have

Page 101

pain with intercourse?

A. Yes. Anytime I'm doing vaginal surgery I mention, you know, bleeding, infection, pain. For most any surgery we do, those are the three most common complications.

Q. Okay. Now, I think you discussed with Counsel that you went ahead and performed the surgery, and implanted the autologous graft. Right?

A. Yes.

Q. And for some reason that autologous graft wound up creating the same sorts of difficulties with urination as her mesh graft created. Is that fair?

A. Not the exact same problem.

Q. Okay.

A. But similar.

Q. Okay. Well, what's the difference in the problem?

A. The difference is it didn't perforate the urethra.

Q. Okay.

A. It was causing obstruction, but not perforation.

Q. Okay. Well, let's -- is it fair to say that she had two types of problems here? One was that she was getting perforation in the urethra and the other was that she was having an obstruction that was preventing her urinating?

A. Yes, that's fair.

Q. Okay. And so I'd like to address those sort of one

Page 102

at a time.
A. Okay.
Q. So if we talk about the difficulty with urination, is it fair to say that that problem was similar when she had the mesh graft and when she had the autologous graft?
A. Yes.
Q. Okay. Was there any difference in it?
A. I think that the big difference was the amount of pain, so the pain was greater when she had the initial issues after Dr. Davis' surgery than after the surgery I did.
Q. And would the pain, would you presume that was associated with a perforation, or with the difficulty with urination?
A. Most likely with the perforation. But certainly patients that are obstructed, especially if they're having urinary tract infections they have pain. They have to do self-catheterization. That in and of itself can be painful.
Q. Now, looking at the obstruction, the difficulty with urination, do you have an opinion as to why that happened with both of her grafts?
A. I can, you know, mention the different causes. But I don't know exactly why it happened twice in this patient.
Q. Okay. Well, Counsel asked you earlier about mesh shrinking, right?

Page 103

A. Mesh contracture? Yes.
Q. Right. Does autologous graft shrink?
A. No.
Q. Okay. So you don't presume that her autologous graft that you put in shrunk, do you?
A. No.
Q. Okay. And yet she had the same problem with it that she had with the mesh graft?
A. She had a similar problem.
Q. Right.
A. She had obstruction, but not perforation.
Q. Okay. So shrinking is not a good explanation for her obstruction, is it?
A. Shrinkage is an explanation, but there's other explanations.
Q. Okay. Well, what are the other explanations?
MR. McCRARY: Are we talking about the first surgery or the second surgery?
MR. MYERS: I'm talking about both of them.
A. Okay. Well, we mentioned earlier that tensioning is a big issue. So how we tension the sling is going to be important on what kind of outcome the patient desires.
(BY MR. MYERS) Q. Do you recall did you have a discussion with her for the second surgery about how much you were going to tension the autologous graft?

Page 104

A. Yes. The discussion was the expectation in a young patient is we would tension it enough that they would be dry; that they wouldn't leak under any circumstance, and they wouldn't have to use a catheter.
So for primary patients and even secondary slings, that's still our goal, to have, you know, the best of both worlds: that you're dry and can urinate normally. That was the goal of the procedure.
Q. Are you familiar with a term called "challenge-dechallenge"?
A. Challenge-dechallenge?
Q. Yes.
A. With respect to voiding dysfunction?
Q. No. Well, I've heard it with respect to, for example, a medication. That a person has a problem, you take it away. And if they have the same problem when the medication isn't there that it probably --
A. Okay.
Q. -- wasn't the medication causing it. Have you heard that --
A. No. It's not --
Q. Okay.
A. -- language I use or I've had people use with me. But I understand --
Q. Okay.

Page 105

A. -- what you're getting at.
Q. So for example, if a person had, you know, if a person was on a medication, they had a problem, you took them off the medication, they still had the problem, you probably wouldn't think it was the medication causing the problem?
A. You'd be, you know, more than likely think that that's --
Q. Okay.
A. -- what was going on.
Q. Okay. And so looking just at Ms. Comer's obstruction, we have a sort of dechallenge here with her mesh, right? Because you took away her mesh, you put on an autologous graft, and she still had obstruction.
So it's not something about the mesh itself that's causing her obstruction. Do you see that reasoning?
A. Yes, I see the reasoning.
MR. McCRARY: Object to form.
It's not a question.
MR. MYERS: Okay. It was a question.
(BY MR. MYERS) Q. Do you see the reasoning?
A. I understand --
Q. Okay.
A. -- you know, that slings can cause obstruction. It's a phenomenon of the sling, not necessarily the biomaterial.

Page 106

Q. Okay. Yes, and I guess maybe I should just ask you this way.

Do you see any basis to see it's something about the material used in the polypropylene itself that caused the problem Amber Comer had with obstruction?

A. That's too specific a question, you know, Andrew. I don't -- all I can say is that regardless of the sling material, slings can cause obstruction.

Q. Okay.

A. That's -- that's a statement I'm comfortable with.

I'm not familiar with the materials science and some of the other implications, you know, that we were talking about earlier.

The incidence of obstruction is lower with the midurethral sling than it is with an autologous sling.

Q. What's the reason for that, that the obstruction would be lower with the mesh than with the autologous?

A. Some of it is the population that's being treated in those two groups. So some of it's more of a phenomena of the patients you're treating. Others is related to the way the procedure's done and the way the tensioning's done.

So with the TVT procedure for instance, the whole genius behind that was that it was tension-free; that you

Page 107

could just lay the mesh in there and, you know, let it have some tissue ingrowth, and it would naturally replace the pubourethral ligament and support the urethra without causing obstruction.

There was really very little if any tensioning required for the procedure, and that's why it became, you know, wildly popular amongst patients and physicians.

The autologous sling is a much more technically demanding procedure done only by a few people. And the tensioning is more -- I should say less precise for that procedure. You have to tension it; you have to tie it down. You're tying knots. And how tight you tie those knots, that can vary a lot based on providers.

Q. Can the patient's anatomy lead to tightening of the sling? That is, can there be inflammation, swelling, something of that nature that leads to the sling to tighten over time?

MR. McCRARY: Are we talking synthetic or autologous?

MR. MYERS: I'm talking about both.

A. I wouldn't use the word "anatomy." So if you're using the word "anatomy" I would say no.

(BY MR. MYERS) Q. Okay. How about tissue?

A. You know, I think the patient's, if the patient has hypermobility, you know, that's one condition. If the

Page 108

patient has a prolapse that's another condition. So there are factors, you know. Let's say there's patient factors that affect sling tension.

Tissue or anatomy, I would hesitate to use those words. I think they're too specific.

Q. Okay. Do you know of any factors in Amber Comer that could have led, in both instances of her getting a sling implanted, to -- for the sling to tighten over time?

A. No. There's no identifiable factors that I see in her case that would have suggested she would've been at higher risk for retention.

Q. Now, turning to talk about the, you know, we were talking about the obstruction. If you turn now and talk about the perforation or the erosion, whatever term we want to use, Counsel was asking about the lysis and takedown that Dr. Davis performed. And you were looking at her surgical note.

And first, do you agree that there was not any sort of hole identified in Ms. Comer's urethra prior to that surgery?

A. Prior to which surgery?

Q. To the sling lysis that Dr. Davis performed on -- what was the date of that surgery? 4-8, 2011.

A. Well, Dr. Davis performed cystoscopy at the time of her Lynx implantation. There was at least no perforation

Page 109

then.

I don't believe she performed cystoscopy until the end of the procedure on April 8th, so she didn't perform cystoscopy before April, you know, say the days immediately before April 8th or, you know, at the time of surgery. I believe she started the surgery and then looked in afterwards.

She didn't look in right at the commencement of the surgery, so it's hard to know when that happened because, you know, there's, you know, she didn't look in until after the surgery started.

Q. And Counsel was asking you earlier that essentially, as I understand it, in the lysis and take-down surgery that occurred in April of 2011, the mesh sling is over the urethra. It's cut away, and there was a hole under it.

Is that fair in layman's terms?

A. I think that's an overstatement.

Q. Okay. How is it an overstatement?

A. Just the way you said that, it just seems overly strong.

Q. Okay.

A. What you said was that when you got in there basically the sling was in half and there was a hole in the urethra. That's not exactly how it looked.

Page 110

Q. Okay. How did it look?
A. In my surgery or Dr. Davis'?
Q. Dr. Davis' surgery.
A. I think Dr. Davis, when she got in there, she mentioned that she could identify the mesh. She didn't identify a hole.
Q. Okay.
A. She passed her right angle around the mesh, and cut the mesh. Once she cut the mesh then she saw the hole.
Q. Okay.
A. So did she not see the hole because the mesh was covering it?
Q. Right.
A. Or was it there or was it not there? We don't really know.
Q. Okay.
A. She didn't look in at the beginning of the surgery.
So to say that when she got in there there was, you know, a hole in the urethra that she was looking at visually, she never mentioned that.
Q. Right, right. I didn't mean to suggest that.
But I guess what I'm meaning to ask is, there's two possibilities here. One is that it's somewhat difficult to pull the mesh away from the urethra, and pulling it away could cause a hole, or there could have been a hole under

Page 111

there to begin with. Is that fair?
A. That's fair.
Q. Okay. And that's, of course, not suggesting that Dr. Davis did anything wrong; it's -- but it's perfectly possible that she, in the process of pulling that and cutting that mesh away from the urethra, could cause a hole?
A. Yeah, certainly.
Q. Okay. And if you look back at Exhibit 4, which is her operative note, Counsel asked you about the description of the operation.
A. Exhibit 4?
Q. Right. So if you look at -- if you look at the second page --
MR. McCRARY: Surgery two?
MR. MYERS: Right.
(BY MR. MYERS) Q. So yes, the 4-8, 2011 surgery.
But if you look up under Findings, Finding No. 2 states, "Urethrotomy resulted when the sling was lysed and was immediately recognized." Doesn't that suggest that she's saying that the urethrotomy resulted from her lysing the sling?
A. If that's what she's suggesting I'm sure --
Q. Okay.
A. -- you've already taken her deposition. If that's what she feels, then that's what she feels.

Page 112

Q. Okay.
A. It's hard for me to say what she was feeling --
Q. Right.
A. -- when she made that statement. But that's her statement, so I would just --
Q. Okay.
A. -- take that at face value.
Q. Okay. But let me just ask you. That's not a particularly surprising thing to happen, and it also doesn't suggest that Dr. Davis did anything wrong, does it?
A. Correct.
Q. Okay. And so if that's the case then, in fact, the mesh did not erode into the urethra?
A. I don't know the answer to that.
Q. Okay.
A. You know, again I think these are statements that are better for Dr. Davis. If you're asking about causation, I don't know what caused the mesh to end up in the urethra, why there was a hole.
All I can say is a hole occurred, or at least was recognized during that surgery.
Q. Okay.
A. That's what we know. Those are the only facts that I think we know unequivocally.
Q. Okay. But however this hole occurred, you believe

Page 113

that this is the same hole that was -- I'm sorry -- that was present later on, right?
A. Maybe not the exact same hole.
Q. Okay.
A. But I would say that she successfully, successfully repaired the hole and -- as I did when I removed the rest of the mesh.
And then the hole that occurred when I was removing or cutting the sling that I placed, I feel that that hole was related to the actual cutting or coming around with the right angle. It's a very difficult thing to do precisely.
Q. Right.
A. You're talking about, you know, a millimeter here.
Q. Right, right. And again, that's not suggesting that anything was done wrong; it's just something that you're cutting in a tiny space and it's right up against, and that's just something that can happen as a result of trying to deal with this adverse effect. Right?
A. Correct.
Q. Okay. But so I just want to make sure we, sure I understand.
So this hole's present. And then when you go and do your initial surgery -- well, actually let's move back a step.
So then when you have your initial visit with

Page 114

Ms. Comer, I believe you said you did cystoscopy.
A. Cystoscopy.
Q. Cystoscopy. And at that point you identified mesh that seemed to be at least against or partially into the wall?
A. So the urethra, think of it as three layers. And it was through the first two layers, and there was just one remaining layer there, the lining, or the mucosa. So it was between the mucosa and the spongy tissue around the urethra.
Q. Okay.
A. So it was right in between, you know, the deepest layer and the middle layer.
Q. Okay. And so your reasoning for taking out the mesh at that point was to make sure that part didn't get all the way through?
A. Correct.
Q. Okay. And then if I understand correctly, when you actually performed the surgery, then you found an actual hole through the urethra as well?
A. I think of the two things one and the same.
When we took the mesh out, you know, those few cells that were lying above the mesh went with it. And that left an opening in the urethra.
Q. Okay.
A. You know, that's how these cases go. The 20

Page 115

or so we mentioned to Amber, the 21 we published on, every one of those patients has an opening in the urethra.
The opening might seal up. As the mesh is in the urethra there might be an entry and exit point, and you have to get into the urethra some way to get the mesh out so you have to, you know, open up the entry point or the exit point or both.
Q. Okay. And so at that point you sealed up the hole that was there?
A. Correct.
Q. Okay.
A. Sutured it up.
Q. Okay. And then -- so then you believe that hole -- so is that hole different then than the one that Dr. Davis noted?
MR. McCRARY: Objection, asked and answered.
A. We don't know.
(BY MR. MYERS) Q. Impossible to tell?
A. Yes.
Q. Okay.
A. I think it's unlikely to be the same opening.
Q. Okay. And then when you performed your surgery to take down your sling, then the one, that one probably is different because that's the one that probably happened from taking down the separate, the autologous sling. Is

Page 116

that fair?
A. We're just essentially in the same area the whole time.
Q. Okay.
A. You know, we're talking about a millimeter here and a millimeter there, you know.
If you have a hole here and there's another hole a millimeter away, one might consider that the same hole, a different hole, you know. We're in the same ballpark.
Q. Now, when you're done with that, after your surgery, and you've stitched these all up, is your expectation that they'll heal?
A. Yes.
Q. Okay. Is the urethra different from other portions of the body in that you expect, when you suture up a wound or a cut, that it will heal up and seal itself?
A. All areas of the body are different. Some are more challenging to heal than others.
The urethra is a very delicate organ. It's a very small organ. It's very close to the surface. So I would say the urethra probably doesn't heal as well as the bladder, say, for instance.
If we have a hole in the bladder, the hole in the bladder's going to heal up a lot better than the hole in the urethra.

Page 117

Q. Do you -- are you aware of any reason to think that the holes, the hole or holes that were in Ms. Comer's urethra, did not heal after her last surgery?
A. After the last surgery with me?
Q. Right.
A. After the February 7, 2012, surgery? No. I believe the holes healed fine.
I examined her afterwards. And it appeared to have healed well. I never did another cystoscopy after that; I'm not aware if another physician may have. She did have the MRI in 2013.
The only access to records I have are the University records. I don't know if she's being treated outside the University. So to my knowledge, the hole has healed up. But I can't say that definitively since I have not seen this patient in, you know, over two years.
Q. And if the hole did heal up, would you expect it to cause any ongoing problems?
A. Not necessarily.
MR. McCRARY: Do you mind if we take two minutes?
MR. MYERS: That's fine.
THE VIDEOGRAPHER: Off the record at 10:18.
(Short break.)
THE VIDEOGRAPHER: Back on the record at 10:46.
(BY MR. MYERS) Q. Doctor, I wanted to hand you what

Page 118

I'm marking as Exhibit 9.
(Exhibit 9 marked for identification.)
Q. I need you to flip back several pages. If you look in the lower right-hand corner there's a Bates stamp ComerA Bolshoun Medical 000113. I actually have here a note here with Dr. Bolshoun, or Ms. Bolshoun I guess it is.
A. Yes, a PA.
Q. She's a PA.
And so this I believe was entered August 23rd of 2012, and if you look under the subjective section it says, "Has dysuria and sharp shooting pains in the urethra. She finished a course of antibiotics and symptoms returned about a week later. Having frequent accidents." Then it says, "She was doing better until two months post-op (approximately late April). Lifted a heavy object and felt a pull in bladder area. Since then she feels there's incomplete voiding and she has accidents."
And so what this seems to be suggesting is that Ms. Comer lifted something heavy in August, two months or I'm sorry, April, two months after the last surgery you performed on her, did something in her bladder, and it made her urinary symptoms worse.
And I ask, I didn't see any note of that in your records. And I take it that's not something that she reported to you. Is that, ask that first. Is that something

Page 119

she ever reported to you?
A. She never, when --
Q. Okay.
A. This never was reported to me.
Q. Okay. And I -- and then, I guess, I would ask whether there's anything you can make of that, whether that's something, you know, knowing the type of graft that you implanted in her, whether that's something that, you know, makes sense to you as a mechanism that she could have torn something.
Or, you know, if it makes any sense to you that there's something that could have happened in there that would have caused an injury that would lead to her worsening urinary symptoms?
MR. McCRARY: Object to form.
A. I think lifting something heavy can cause the sling to break and maybe have recurring incontinence, but not dysuria, not bladder incomplete emptying.
You know, the symptoms are pretty inconsistent. Is it incontinence or is it incomplete emptying? Which is it?
And, you know, the more likely explanation you can see on the next page she had a urinary tract infection. She had Klebsiella in her urine. And, you know, that's, probably --

Page 120

(BY MR. MYERS) Q. Okay.
A. -- a more common cause of dysuria in the female would be a urinary tract infection.
Q. Okay. Well, could it be both, that she had a urinary infection and that she tore her sling?
A. It's unlikely.
Q. Okay.
A. Yes. The autologous sling almost never breaks. It's a very robust procedure.
Q. Would there be a way to find out if she had torn her sling?
A. You -- probably the best way is just follow her history and see what happens over the next few years.
If this was an isolated event and went away and she didn't have any subsequent issues, it was probably something more transient like a UTI, you know.
And if she, in 2014, is not leaking urine, I think it's very unlikely she tore her sling.
Q. Okay. Your last surgery was to loosen the sling, right? It should still be in place, right?
A. Yes. Loosening the sling or cutting the sling does decrease the integrity of it. But usually there's still enough remaining support laterally that will allow the patient to maintain continence.
Q. Okay. But if she's complaining today that she is

Page 121

having complete stress urinary incontinence, would it make some sense to you that perhaps she did tear the sling?
A. I don't believe she's complaining of that, so I don't see any evidence --
Q. Okay.
A. -- that she's complaining of that.
Q. Okay. Well, well, I realize, I realize she hasn't come in and followup. But if she's claiming, for example, in this litigation that she's having basically worse urinary incontinence than she's ever had --
A. I don't have a copy of her complaints.
Q. Okay, right, okay.
A. Maybe Sean has that. But I don't -- I don't know what --
Q. Okay.
A. -- her complaints are at this point, what her --
Q. Okay.
A. -- what she's alleging.
Q. Okay. But I take it -- so if I understand what you're saying, what she's recounting here couldn't cause incomplete emptying. If it could cause anything it would be the sling's gone, and it would just be complete incontinence. Is that fair?
A. You know, if you lift something heavy you might loosen your sling. I wouldn't expect that to tighten the

Page 122

sling.
Q. Okay, fair enough.
If I could get you to look at your last, I believe this is your last visit with her, which would be dated I believe it's -- I get confused about the entered versus the visit time. I believe it's April of 2012.
A. April 6, yes.
Q. Okay.
A. 2012.
Q. Okay. So if you look under the assessment and plan, the first statement is, "Doing better now that mesh is removed."
What did you mean by that?
A. I believe her urethral pain was improved but not cured. And so I recommended that she have physical therapy for the residual pain. And I did write a prescription or order, if you will, for that.
I discussed with her Lyrica, which is a drug for neuropathic pain. And I talked to her about it. I don't know if she actually took that.
You know, Amber has a number of psychotropic medication she's taking, you know, as the baseline. So I may have deferred to Patricia Bolshoun to prescribe that.
Q. Okay. And you're referring there to the fact that she already takes Xanax?

Page 123

A. Xanax, and I think she's been on antidepressants as well --
Q. Okay.
A. -- at different time points.
Q. And if she is -- your recommendation here is that she have pelvic floor physical therapy. So if she is having residual pain, would that be your No. 1 recommendation for her to treat it?
A. For her, yes. I think, you know, that I felt that she had a very complete mesh explantation from the surgical standpoint. And we didn't have any explanation or solutions, and so, you know, to try to treat that with therapy as well as medication.
Q. Okay. And so in your opinion, the most likely thing to help her would be physical therapy?
A. Yes.
Q. Okay. And then the next most would be Lyrica?
A. The two in combination. I wouldn't necessarily prioritize them.
Q. Okay. But that, if she came to you today and said, I'm still having problems with this you'd say, Try that physical therapy?
A. I would discuss both therapies with her.
Some patients prefer a non-pharmacologic solution, physical therapy. You know, others say, I don't have time

Page 124

for that. Medication. Some say, Just get me out of pain. Both.
Q. Okay. And you also say here, Return for followup as needed.
What exactly does that mean?
A. That means at her discretion.
Q. Okay.
A. That I wasn't going to schedule her for any further followup; that I was satisfied with the outcome at that point.
Some patients we have to ask them to come back regularly because they could have something going on that they may not be aware of so they need some periodic review. Others, you know, have a better understanding about when there's an issue, and they'll come in.
Amber, with her anxiety disorder, with her frequent visits and phone calls, I had no concern that she wouldn't come back if there was a concern.
Her primary care doctor was here; her urogynecologist was here; all of her doctors were University doctors. I know all of them well. So at that point I said, you know, Come back if you need to.
Some patients we have to tell them to come back because they don't know when they need to.
Q. But from your point of view she didn't have a

Page 125

problem that said, You need to come back within six months or a year or something like that for me to follow you?
A. That's correct.
Q. Okay. But at the same time you made clear to her, If you're having problems with pain or you're having problems with your urination you ought to come back?
A. Yes. And she also had Dr. Davis following the whole time.
Q. Okay.
A. And in order to try to reduce the number of visits for this patient and the expense, you know, to everyone that she'd incur, that trying to simplify her care. I have a close working relationship with Dr. Davis. I knew Dr. Davis would get me involved again if she felt it necessary or if Amber felt it necessary.
Q. You said something about, you know, her anxiety disorder, and you said she had a number of visits and calls. What was that referring to?
A. I'm not trying to imply anything.
Q. Okay.
A. I'm just saying that, you know, that Amber probably would call more frequently than most patients. And so I knew that she was a very responsibile patient, and if there was a concern she would let us know.
Q. Okay. I take it as of today you have no knowledge

Page 126

of her having ongoing problems either with pain or urination, stress urinary incontinence?
A. At least from review of the University records. When I reviewed the records last night I looked up to the most recent visits, not only of my own but of other providers in our system. So I didn't see really much in the last few years here.
Q. Okay. So based on what she's reported to the clinic here, this is not an ongoing problem for her?
A. What's not an ongoing problem?
Q. Pain, stress urinary incontinence.
A. I don't see either of those two things being an ongoing problem for her.
Q. You were asked earlier about whether you received instructions about how to remove mesh from medical device companies.
Do medical device companies provide instructions to you on most of your surgical techniques?
A. On implantation techniques, yes. On explantation techniques, no.
Q. Right. Well, aren't there a lot of surgical techniques you use that are part of your training and expertise as a surgeon that you don't need a medical device company to tell you about?
A. Sure. That's why we do a residency and fellowship

Page 127

and seven years of postgraduate training.
Q. Okay. And you were asked a lot of questions about your experience with Ethicon as a consultant, as a trainer.
I'll ask you first, have you ever had any sort of relationship as a trainer or a consultant with Boston Scientific?
A. I have not.
Q. Okay. Is there a reason for that? Have you ever been approached? Or is it just something that's never come up?
A. Generally the people they ask to train are people that are experienced with their products. So I had a lot of experience with Ethicon's products; hence, they asked me to train physicians on their behalf.
Up until recently probably I'd only used Boston Scientific's products sparingly. So they're not going to ask someone who doesn't have the experience with their products to train people how to use their products.
Q. And do you recall having any contact with Boston Scientific sales representatives?
A. They would call on me over the years. Certainly they were calling on Dr. Davis.
I remember various sales representatives. You'd see them in the hospital, maybe in the lounge or they'd, you know, leave you a handwritten note or something in the

Page 128

office. But nothing more than that.
Q. Can you recall ever talking to anyone from Boston Scientific about the Lynx device?
A. No. They never detailed me on the Lynx device. They knew that I was probably happy with the devices I was using.
Q. The training experience that you had with Ethicon, did you find that to be a valuable professional experience for you and for the people who you were training?
A. Absolutely. I felt that I had an ethical, moral obligation, if you will, to help train people to use the products properly.
And I'm always willing to help people if they ask for help. So people that I had trained, a lot of them I have maintained relationships with. People would call me on my cell phone or email me and present cases to me and ask me for advice.
That's what we do as a professor, you know. We teach people.
MR. MYERS: I think that's all the questions I have.
MR. McCRARY: Doctor, I have a couple more followups. We'll get you out of here by 11:00 as promised.
THE WITNESS: Okay.
EXAMINATION
BY MR. McCRARY:

Page 129

Q. This AUA statement that we looked at that Counsel provided to you here, this one right here --
A. Yes.
Q. You see the bottom part where it says, "The AUA strongly agrees with the FDA that a thorough informed consent be conducted prior to synthetic sling surgery. The AUA also agrees that surgeons who wish to perform synthetic sling surgery should: undergo rigorous training in the principles of pelvic anatomy and pelvic surgery, be properly trained in specific sling techniques, and be able to recognize and manage complications associated with synthetic mesh sling placement."
Do you see that?
A. I do.
Q. Do you agree with that?
A. Yes.
Q. Do you know if Boston Scientific, or any other mesh manufacturer for that matter, requires a physician to be certified before they're allowed to implant mesh devices?
A. I don't know what the standards are amongst the manufacturers. "Required" might be too strong of a word.
Q. Do you know if there's a certification process?
A. No. There -- that's not their role to certify or credential physicians. That's the role of the hospital

Page 130

credentialing and privileges committees and the department chairs and division chiefs to determine what procedures the members of their department are capable of doing.
Q. So you think that's not a responsibility of the medical device company?
A. No. I don't feel that that's their responsibility.
I think they should create opportunities for training and offer advice, offer professional education, provide, you know, disclosures about their products and scientific data.
But it's not, it's not their responsibility. I think that's probably too strong of a word.
Q. Okay. I want to talk to you, are you able to tell me what the cost of a synthetic sling implantation procedure is here at the University?
A. You'd have to be more specific about cost. The cost of the surgery? The cost of the hospital stay? What the surgeon's fee is? What they actually pay for the mesh?
Q. I really want to know all that. Like for Ms. Comer, what's an approximate value that she would have paid to get the Lynx implanted?
A. I can just tell you the numbers I know. You know, a physician typically would be reimbursed somewhere around four to five hundred dollars for doing a sling, whether that's a mesh sling or a biological sling. Whether it takes

Page 131

them a half hour or two hours you get paid the same. It's based on the CPT code.
The hospital -- the hospital, they purchase the mesh slings. They might be priced anywhere from $600 to as much as $1,200. The overwhelming majority of the cost is to the hospital care.
So if it's an outpatient procedure there's going to be cost to the anesthesiologist, the recovery room, pharmacy. That stuff typically adds up to at least $10,000.
So, you know, 90, 95 percent of the cost, you know, for healthcare is related to the hospital cost. Five percent typically is physician, and then five percent, you know, towards the product.
Q. So is somewhere in the ballpark of $10- to $15,000, all things considered, an accurate estimate of the cost to have a Lynx implanted here at UC Denver?
A. Yes. It's probably somewhere between 10, 15. Again, I don't -- I don't have a private practice; I don't do the billing and collecting. So I'm, you know, making estimates.
Q. I understand. What about for a sling lysis procedure?
A. I think it would be almost the same cost. Each one of those surgeries are virtually the same because you can see the cost of the mesh is very little. It's the cost to the

Page 132

hospital where the majority of the cost is.
Q. And what about the procedure that you performed, the mesh removal and implantation of the autologous graft?
A. That would probably be even more expensive because she had an inpatient stay. I believe she had an inpatient stay probably with the initial surgery because she had a hysterectomy.
So if you add the cost of the hysterectomy into it, that's probably another 15,000, push it up around 25,000. So the surgery she had with me with the mesh removal and autologous sling was probably around $25,000.
Q. And would the cost of lysing that autologous graft be the same as the cost to lyse the synthetic sling?
A. If they were both outpatient procedures, the cost would probably be virtually identical.
Q. And with Ms. Comer, were they both outpatient procedures?
A. As far as I could tell they were.
Q. Okay. Now, when Ms. Comer first presented to Dr. Davis, did you see that she had some complaints of pain at that time that were attributed to fibroids?
A. Yes. When she was I think seeing Dr. Appleton was her gynecologist.
Q. And were her leakage complaints the reason that

Page 133

she was there for that visit? Or was that a secondary complaint?
A. With which doctor?
Q. Appleton.
A. With Dr. Appleton I believe the complaint was for pain and fibroids. And then Dr. Appleton consulted Dr. Davis for the urinary complaints.
Q. Okay. Do you think that she should've tried anything more conservative before having a sling implanted?
A. I don't know the answer to that. I really don't know how severe her incontinence was and what exactly pertained to her history.
Oftentimes patients will have slings implanted at the time of hysterectomy because there's an opportunity there. They're having anesthesia anyway. And if they feel this procedure's going to be inevitable, then they may want to have it done at that time in order to have one recovery instead of two recoveries.
Q. You mentioned a minute ago when Counsel was asking you questions that today you perform mostly retropubic sling procedures. Right?
A. Yes.
Q. And you mentioned in the past you've had times where you did mostly transobturators and also the mini-slings. Is that accurate?

Page 134

A. That's accurate.
Q. Why the change?
A. I think what I was mentioning earlier is largely because of the medical-legal environment that we are in that I'm trying to do the most conservative procedures that give great benefit to my patient, and doesn't create professional risk for me or this hospital.
Q. Does it have anything to do with your experience in using those different techniques? Have you found that the retropubic approach is less likely to cause complications?
A. It's actually more likely to cause complications. If you look at some of the recent statements if you include, you know, a trocar injury at the time of surgery, you put that in the mix, it's probably a more complicated procedure, but a more efficacious procedure and a more well-studied procedure.
The mini slings and the obturators, you know, have very good results in the short term, but maybe slight efficacy in the long term.
The mini slings especially are not that well studied. And I know that the FDA has ordered some reinvestigation on those products through the 522 process.
So any product that's under 522 review we've generally made a decision as a group not to use until we see the conclusions of those products. So we don't use any of

Page 135

the products under 522 review, so that just leaves us with obturator and retropubics.
So it was a decision I made. But we have obturator slings available on our shelves. I have partners that do the obturator slings fairly regularly.
Q. I apologize I didn't ask you this earlier when we were talking about the costs that Ms. Comer has incurred in having these surgeries.
But is it your understanding that she was on disability for part of the time that she was having these procedures done?
A. I saw, yes, records in the chart from both Dr. Davis and PA Patricia Bolshoun on filling out FMLA paperwork. Whether that was short-term disability or long term I'm not sure the extent of that.
But I know that she was probably unemployed most of that year. Or not unemployed. I should say disabled most of the year.
Q. And you're not surprised by that given the complications that she faced, right?
A. No, I'm not surprised by that.
Q. Right. Counsel asked you some questions about whether the urethrotomy that Dr. Davis found could have been the result of her pulling the mesh away from the urethra. Do you recall that?

Page 136

A. Yes.
Q. If that was the case, wouldn't that indicate that the mesh had eroded into the urethra?
A. I didn't -- I'm not going to make a statement on that, Sean. We've been through this. I mean, you're getting into issues on causation. And so, you know, I went over the possible causes. But I'm uncertain what exactly happened here.
We know that the mesh ended up in the urethra. We know that there was a hole in the urethra. How that happened or why that happened, I'm not really here to make statements on that. I'm just here to say what we did to help Amber.
Q. So you're not offering any opinions as to what caused her -- the hole in her urethra?
A. No. I think I've been pretty clear throughout the deposition that I'm not here as an expert witness. I'm here as a treating physician. I'm not offering opinions on what caused this.
I didn't do the original surgery. I feel if you're looking for answers there, Dr. Davis may have a better understanding on why this happened.
Q. Right. And the reason I'm asking you is because you seem to be the guy in part of the entire country who sees mesh complications; and therefore, I would think that you do have some sort of expert, expertise in dealings with

Page 137

complications and may know more than the average physician about why they may occur.
MR. PICHE: I'm going to object to the form of that. I don't think it's a question, and it's getting a bit argumentative.
I think he's repeatedly stated that he is -- doesn't have an opinion as to causation and is not going to give one.
So I -- would you please move on from that.
MR. McCRARY: Yes, I will. And so you're going to instruct him not to answer that?
MR. PICHE: He has answered it and has answered it several times already.
So, you know, that's, he doesn't have an opinion to give so there's nothing to give, so there's nothing to instruct him not to give.
MR. McCRARY: All right. That's all I got.
CROSS-EXAMINATION
BY MR. MYERS:
Q. Let me just ask, follow up on one thing.
Counsel asked you about in Exhibit 8 the AUA statement, the description of the training that physicians ought to have if they're going to implant slings.
Do you think that you and Dr. Davis have the sort of training that that statement says physicians ought to have if they're going to implant slings?

Page 138

A. Yes, certainly we do. And, you know, we train young physicians every day in our practice, our residents and our fellows on how to do these procedures properly.
Q. And clearly you are not only trained, but you're a person who trains? You're an expert on pelvic surgeries, right?
A. I have expertise --
Q. Okay.
A. -- in pelvic surgery. I'm board certified in female pelvic medicine. I have a fellowship here I'm the director of. So I've spent a significant amount of my life developing expertise in this area.
Q. Okay. But we can agree that you shouldn't walk across the street and perform heart surgery, right?
A. Yes, sure, certainly.
Q. Okay. And it's not a pacemaker company's job to make you not go perform a heart surgery, right?
A. You know, what I do is really up to me and the hospital, and what they allow me to do and what they credential me to do.
Q. Right. And every physician uses professional judgment, along with a hospital, to decide what they're qualified to do and where their comfort level is in performing surgeries. Is that fair?
A. Every prudent physician should.

Page 139

MR. MYERS: Okay. That's all the questions I have.
MR. McCRARY: I'd like just an e-transcript, scanned exhibits, and at one point I'd like a rough.
MR. MYERS: Standing order.
THE VIDEOGRAPHER: This is the end of DVD No. 2 of 2 in the video deposition of Brian J. Flynn, M.D. Going off the record at 10:55 a.m.
(Proceedings adjourned.)

Page 140

C E R T I F I C A T I O N

I, Martha Loomis, Certified Shorthand Reporter, appointed to take the deposition of
BRIAN J. FLYNN, MD,
certify that before the deposition the deponent was duly sworn to testify to the truth; that the deposition was taken by me on August 29, 2014, then reduced to typewritten form by means of computer-aided transcription; that the foregoing is a true transcript of the questions asked, testimony given, and proceedings had.
I further certify that I am not related to any party herein or their counsel, and have no interest in the result of this matter.
IN WITNESS WHEREOF, I have hereunto set my hand this 5th day of September, 2014.

_____
Martha Loomis
Certified Shorthand Reporter

Proofread by E.Williams